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SPLITTING SCALES: CONFLICTING NATIONAL AND REGIONAL ATTEMPTS TO MANAGE COMMERCIAL AQUACULTURE IN THE EXCLUSIVE ECONOMIC ZONE

Brandee Ketchum[*]

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I. INTRODUCTION

Like other environmental resources subject to public use, various interest groups struggle over joint management of scarce fisheries resources. Further, differing goals for resource management, such as financial goals versus conservation goals, frequently pit regional groups against one another. In some cases, regional interests

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may conflict with overall national interests. As goes the water and the air, so go the fish.

Congress passed the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) in 1976 to address overfishing in the Nation's waterways.[1] Eight Regional Fishery Management Councils were given authority to manage fisheries in distinct geographic regions, with the instruction to "exercise sound judgment in the stewardship of fishery resources" through a cooperative of state and fishing industry representatives and environmental and consumer groups.[2] One such council is the Gulf of Mexico Fishery Management Council (GMFMC - the Council), which operates as a "quasi-federal entity" whose rules must be approved by the National Marine Fisheries Service (NMFS), the lead federal agency over fisheries and marine life within the National Oceanic and Atmospheric Administration (NOAA).[3] The Council includes representatives from Louisiana, Mississippi, Texas, Alabama, and Florida. Its primary function is to establish a Fishery Management Plan (FMP) that prevents overfishing in its regulatory geographic region, while maintaining the optimal yield of several varieties of marine life.[4]

Following enactment of the Magnuson-Stevens Act, the NOAA began a research and development program concerning "marine, estuarine, and anadromous species"[5] aquaculture, or fish farming.[6]

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1. 16 U.S.C.A. §§ 1801 *et seq.* (2007) *amended by*, Pub. L. No. 104-297, 110 Stat. 3559 (1996) (the Sustainable Fisheries Act of 1996) (2007). On Jan. 12, 2007, President Bush signed the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006, Pub. L. No. 109-479, 120 Stat. 3575 (2007), setting a firm deadline to end overfishing in America by 2011 and use "market-based incentives" to double the number of limited access privilege programs, which assign specific annual harvest quotas to eligible fishermen and regional fishery associations. WHITE HOUSE OFFICE OF THE PRESS SECRETARY, FACT SHEET: *MAGNUSON-STEVENS FISHERY CONSERVATION AND MANAGEMENT REAUTHORIZATION ACT* (Jan. 12, 2007), *available at* www.whitehouse.gov/news/releases/2007.

2. 16 U.S.C.A. § 1801(b)(5)(2007). "The Gulf of Mexico Fishery Management Council shall consist of the States of Texas, Louisiana, Mississippi, Alabama, and Florida and shall have authority over the fisheries in the Gulf of Mexico seaward of such States." *Id.* at § 1852(a)(1)(E).

3. The characterization of the Gulf of Mexico Fishery Management Council as a "quasi-federal entity" comes from Wayne Swingle, former Executive Director of the Council. Email from Wayne Swingle (March 24, 2008) (on file with author).

4. 16 U.S.C.A. §§ 1851(a)(2) & 1852(h)(2007).

5. An "anadromous species" is a species of fish which spawns in fresh or estuarine waters of the United States and which migrate to ocean waters. 16 U.S.C.A. § 1802(1)(2007).

Aquaculture is defined as "the propagation and rearing of aquatic species in controlled or selected environments."[7] Prior to 1996, this program mainly consisted of research and development used by commercial fisheries to develop technologies for farmed salmon, shellfish, and shrimp culture operations throughout the United States and the world, including operations in Norway, the United Kingdom, and Chile.[8] However, the 1996 Sustainable Fisheries Act amendments to the Magnuson-Stevens Act delegated regulatory responsibility for aquaculture development in the Exclusive Economic Zone of the United States to the National Marine Fisheries Service.[9] The Exclusive Economic Zone (EEZ) occupies an area between twelve miles and 200 miles offshore, including areas contiguous to United States commonwealths, territories, and possessions.[10] Although the NMFS has the authority to regulate aquaculture development in the Exclusive Economic Zone, no current regulatory scheme provides a clear mechanism to allow commercial aquaculture in federal waters.[11] The NMFS currently requires an "exempted

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6. National Oceanic and Atmospheric Administration, [*NOAA's*] *Aquaculture Policy* (February 1998), at 1, *available at* http://aquaculture.noaa.gov/pdf/17_noaaAqpolicy.pdf. The federal definition of aquaculture comes from the 1980 Memorandum of Understanding between the US Departments of Agriculture, Commerce, and Interior. *Id.*

7. *Id.*

8. *Id.* at 2.

9. *Id.* at 3. Such authority comes from the Act's broad definition of "fishing," which covers the harvesting of fish. 16 U.S.C.A. § 1802(16)(2007).

10. The EEZ is to be distinguished from "state waters," which were defined in the Submerged Lands Act as an area three nautical miles seaward from the baseline (the boundary line dividing the land from the ocean). 43 U.S.C.A. § 1312 (2006). *See also,* NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, *AN OCEAN BLUEPRINT FOR THE 21ST CENTURY,* 70-72, [HEREINAFTER OCEAN BLUEPRINT] *available at* http://oceancommission.gov/documents/full_color_rpt/03a_primer.pdf. Each coastal nation is allowed to establish an exclusive economic zone for the purpose of exploring, managing, conserving, and exploiting living and nonliving resources in ocean waters or in the seabed or subsoil. 1982 UN Convention on the Law of the Sea, 1833 U.N.T.S. 397 (1994). President Reagan declared the US EEZ in 1983. OCEAN BLUEPRINT, *supra,* at 72. *See also,* 16 U.S.C.A. § 1802(11) (defining EEZ for purposes of the Magnuson-Stevens Act).

11. National Oceanic and Atmospheric Administration, The National Offshore Aquaculture Act of 2007, http://aquaculture.noaa.gov.us/2007.html (last visited Mar. 29, 2010). *See also,* Alison Rieser, *Defining the Federal Role in Offshore Aquaculture: Should it Feature Delegation to the States?,* 2 OCEAN & COASTAL L.J. 209, 220-23 (1997) (describing the lack of a cohesive mechanism to permit commercial aquaculture amongst the various federal and state agencies involved in aquaculture management); Erin R. Englebrecht, Comment, *Can Aquaculture Continue to Circumvent the Regulatory Net of the Manguson-Stevens Fishery Conservation and Management Act?*,

fishing permit" to conduct aquaculture in federal waters; furthermore, an exempted fishing permit only allows for the harvest of species managed under a fishery management plan for "limited testing, public display, data collection, exploratory, health and safety, environmental cleanup, and/or hazard removal purposes."[12]

Commentators are engaged in an ongoing debate regarding whether and on what scale the United States should begin large scale commercial offshore aquaculture.[13] In part because no overarching federal regulatory scheme controls commercial aquaculture, any offshore aquaculture that develops is subject to a myriad of federal environmental laws. Furthermore, many coastal states have statutes regulating aquaculture in their own waters (near-shore aquaculture). Criticism of this multi-pronged regulatory approach[14] has led to two concurrent developments with divergent interests: 1) a proposed amendment to the Gulf of Mexico Fishery Management Council's Fishery Management Plan to "provide for the regulation of offshore marine aquaculture," and 2) the creation of a yet-to-be enacted national regulatory program, dubbed the National Offshore Aquaculture Act, "for the establishment and implementation of a regulatory system for offshore aquaculture" in the United States Exclusive Economic Zone.[15] The differing regulatory approaches pit region against region, and regional interests against national interests. Without a well-defined regulatory framework, the Gulf of Mexico's Fishery Management Plan amendment to begin offshore aqua-

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51 EMORY L.J. 1187, 1201-04 (2002) (addressing the inadequacies of the current federal and state regulatory scheme).

12. 50 C.F.R. § 600.745(b)(1) (1996).

13. For example, Jeffrey Sachs, Director of The Earth Institute at Columbia University, argues strenuously for environmentally sound cultivation of herbivorous aquatic species, as opposed to harvesting such species, to relieve pressure on oceans. *See generally*, JEFFREY D. SACHS, COMMON WEALTH: ECONOMICS FOR A CROWDED PLANET (Penguin, 2008).

14. *See generally*, Rieser, *supra* note 11; Englebrecht, *supra* note 11. Furthermore, according to the NOAA, "[c]urrent U.S. law does not provide clear mechanisms to allow commercial aquaculture operations in federal waters. . . . That regulatory uncertainty is widely acknowledged as the major barrier to the development of aquaculture in federal waters." http://aquaculture.noaa.gov/us/2007.html.

15. Gulf of Mexico Fishery Management Council & NOAA National Marine Fisheries Service, Public Hearing Draft: Generic Amendment to The Gulf of Mexico Fishery Management Council's Red Drum, Reef Fish, and Stone Crab Fishery Management Plans and the Gulf of Mexico and South Atlantic Fishery Management Council's Joint Spiny Lobster and Coastal Migratory Pelagics Fishery Management Plan to Provide for the Regulation of Offshore Aquaculture (Dec. 07, 2007) *available at* www.gulfcouncil.org/Beta/GMFCWeb/Aquaculture/Aqua-amend% 20DP EIS%20120707%20with%20indey.pdf).

culture permitting has entered into effect by operation of law due to NOAA's failure to approve, partially approve, or disapprove the GMFMC's actions.[16]

This Comment will examine the issues that frame the aquaculture debate. These issues include economic reasons to engage or not engage in federally sponsored large-scale commercial aquaculture, possible environmental damage caused by aquaculture facilities, and the lack of a comprehensive scheme to regulate commercial aquaculture. The Comment will then review the two currently debated plans to implement commercial offshore aquaculture – the amendment to the Gulf Council's Fishery Management Plan and the federal regulatory program proposed by Congress. A review of these issues leads the author to two conclusions. First, for both economic and environmental reasons, the United States should not engage in large-scale offshore commercial aquaculture, insofar as such plans are currently being debated. However, this conclusion is moot; undoubtedly, the United States is headed towards large-scale offshore commercial aquaculture. The second conclusion is that given that we are headed in such a direction, the comprehensive federal regulatory scheme proposed by Congress provides a better vehicle through which to manage both commercial objectives and environmental concerns.

II. AQUACULTURE'S BACKGROUND

> Peering through the taut weave of polymer netting, a diver could easily believe the sea holds a limitless supply of fish. Inside the submerged cage, tens of thousands of sleek carnivores rub fins as they navigate their salt-water territory.[17]

Aquaculture is considerably more prevalent in other areas in the world than in the United States. In 2004, countries in Asia and the Pacific region accounted for over ninety percent of the world's aquaculture product supply, with China leading production at over sixty-five percent.[18] North America contributed only slightly over one percent to the world's supply of aquaculture production.[19] Amongst that one percent, channel catfish continues to be the most

16. 16 U.S.C.A. § 1854(a)(3) (requiring the Secretary to approve, partially approve, or disapprove an amendment to a region's Fishery Management Plan).

17. David Helvarg, *Farming's New Wave*, POPULAR MECHANICS, Aug. 2005, at 46.

18. Food and Agriculture Organization of the United Nations, THE STATE OF WORLD FISHERIES AND AQUACULTURE 2006, 16 (FAO 2007). The FAO estimations include both food fish and aquatic plants.

19. *Id.*

popular food fish product in the United States, and Atlantic and Pacific salmon in Canada.[20] Although the United States is only eleventh in volume of aquaculture producers, it is the third largest consumer of seafood in the world.[21] In 2006, the United States imported $13.4 billion in edible fishery products, fifty-seven percent of which was from Asia alone.[22] In contrast, the United States only exported $4.2 billion in edible fishery products,[23] leaving the economy with a $9.2 billion trade deficit. The federal government estimates the by 2025, there will be a 2-4 million ton domestic seafood gap in the United States, based on demand growth projections.[24] The rapid expansion of aquaculture worldwide has been coined "The Blue Revolution," mirroring "The Green Revolution" of the 1950s that led to higher grain yields in agriculture.[25]

While the federal government has been involved in the production of fish culture research and development since the late 1800s, the focus has been on "restoring and enhancing domestic freshwater and anadromous species in inland waters."[26] By the late 1970s, however, the increasing trade deficit for fishery products led to the National Aquaculture Policy Act of 1980, designed to "promote the economic development of the industry to augment the commercial and recreational fisheries in the United States."[27] In 2001, the Joint Subcommittee on Aquaculture released an updated National Aquaculture Development Plan which emphasized reducing the trade

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20. *Id.* at 17.

21. *Id.* at 16.

22. National Marine Fisheries Service, *Fisheries of the United States 2006*, 48 (July 2007), *available at* http://www.st.nmfs.noaa.gov/st1/fus/fus06/.

23. *Id.*

24. NOAA Aquaculture Program, *Quick Stats* (March 12, 2007), *available at* www.aquaculture.noaa.gov.

25. Jeffrey D. Sachs, *The Promise of the Blue Revolution*, SCIENTIFIC AMERICAN, (July 2007). *See also*, Susan Stonich, *Resisting the Blue Revolution: Contending Coalitions Surrounding Industrial Shrimp Farming*, HUMAN ORGANIZATION (Spring 2000).

> As the Green Revolution was acclaimed as the means to end world hunger, the Blue Revolution often is hailed as a way to increase incomes and the available supply of affordable food among the poor in the third world. As the Green Revolution was necessary to the establishment of the global agro-food system, the Blue Revolution is an essential part of integrating many important aquatic species and coastal ecosystems into that same global system.

Id.

26. *See* Englebrecht, *supra* note 11, at 1191.

27. *Id.*

deficit in farmed fish products by commercial expansion into the Exclusive Economic Zone.[28]

A. Current United States Finfish Aquaculture Production

Marine aquaculture is "analogous to terrestrial farming and involves some form of intervention in the rearing process to enhance production, such as regular stocking, feeding, and protection from predators."[29] Five finfish (as opposed to shellfish) farms currently operate in the United States; none exist in federal waters or operate in the Gulf of Mexico.[30] In Hawaiian waters, Hukilau Foods grows Pacific threadfin (moi - *polydactylus sexfilis*) and Kona Blue Water Farms grows amberjack (kampachi).[31] Sanapperfarm, Inc. grows cobia (lemonfish - *rachycentron canadum*) and mutton snapper (*lutjanus analis*) off of the coast of Puerto Rico.[32] The University of New Hampshire operates an Open Ocean Aquaculture demonstration project that raises halibut, haddock, flounder, and cod in New Hampshire waters.[33] Finally, Isle of Shoals Mussels operates a commercial longline mussel operation begun by New Hampshire commercial fishermen.[34]

Hukilau Foods operates four open ocean cages located two miles offshore and 40 feet under the surface, under a lease from the Hawaiian government.[35] The submerged cages produce about 900,000 pounds of fish per year, with plans to increase production to around 1.5 million pounds.[36] Formerly Cates International, Inc., the company became the first open ocean farm in the United States in 2000, established after a successful Open Ocean Aquaculture Demonstration Program run by the University of Hawaii.[37] In 2003, Hukilau posted $1.4 million in moi sales.[38]

Kona Blue was founded in 2001 and uses an inclusive "hatch-to-harvest" approach to aquaculture, wherein eggs hatch in controlled

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28. *Id.* at 1192 (citing JOINT SUBCOMMITTEE ON AQUACULTURE, 2000 ACTIVITIES (2000)).
29. Draft Amendment, *supra* note 15, at 6.
30. *Id.* at 11.
31. *Id.*
32. *Id.*
33. *Id.*
34. Draft Amendment, *supra* note 15, at 11.
35. Hukilau Foods, www.hukilaufoods.com/about_us (last visited Mar. 29, 2010).
36. *Id.*
37. *Id.*
38. Draft Amendment, *supra* note 15, at 11.

technological fishery conditions and fish are grown in open ocean pens half a mile off of the Hawaii coast.[39] Kona Blue's process differs from Hukilau's process, in that Hukilau relies on capturing wild fingerlings to stock its cages, whereas Kona Blue actually hatches its own eggs.[40] Kona Blue currently operates eight submersible cages at a total company investment of $33 million.[41] According to the company, Kona Blue furthers "the ancient Hawaiian tradition of aquaculture by leveraging innovative, state-of-the-art hatchery and open ocean grow-out technology."[42] The University of New Hampshire Open Ocean Aquaculture project began in 1997; while it does not sell fish commercially, its technology is in active use at Kona Blue Farms.[43] The project also developed a process for culturing blue mussels; this process has already been picked up by the Isle of Shoals group, which produces 180,000 pounds of mussels annually.[44]

Snapperfarm, Inc. operates submerged cages thirty-five feet below the ocean surface off the coast of Culebra, Puerto Rico.[45] Snapperfarm's goal is to take advantage of "one of mankind's last great frontiers and untapped resources."[46] By 2003 the company produced 50,000 pounds of fish, and it is now considering cultivation of the Caribbean spiny lobster (*panilirus argus* - known to many folks as crawfish).[47] Each of the cages at Snapperfarm is attached to a 25,000 pound concrete block resting ninety-three feet below the seabed surface; the only thing that separates 15,000 fish from circling sharks is the eighty-five foot wall of Spectra netting,[48] "[resembling] a sunken spacecraft."[49] The project operates three fish cages.

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39. Kona Blue, http://www.kona-blue.com/sustainability.php (last visited Mar. 29, 2010).

40. *Id. compare with* Hukilau Foods, http://www.hukilaufoods.com/about.us (last visited Mar. 29, 2010).

41. Draft Amendment, *supra* note 15, at 12.

42. Kona Blue, http://www.kona-blue.com/sustainability.php (last visited Mar. 29, 2010).

43. Atlantic Marine Aquaculture Center, http://ooa.unh.edu/about/about_what.html (last visited Mar. 29, 2010).

44. Draft Amendment, *supra* note 15, at 12.

45. *Id.*

46. Snapperfarm, http://www.snapperfarm.com/2006/aboutopenoceanaquaculture.htm (last visited Mar. 29, 2010).

47. *See* Draft Amendment, *supra* note 15, at 12.

48. Helvarg, *supra* note 1, at 47.

49. Elizabeth Querna, *Fixing Fish Farms*, US NEWS & WORLD REPORT, Aug. 2004, *available at* http://www.unbsj.ca/sase/biology/chopinlab/articles/files/fixing%20fish%20farms%20US%20NEWS.pdf.

Although there are only five such projects currently operational, other companies have submitted lease applications to the state to operate more farms off the coast of Hawaii.[50] Furthermore, the Hubbs-Sea World Research Institute has leased an oil platform in federal waters off the coast of California to conduct a study of the feasibility of using offshore oil platforms for the development of marine aquaculture;[51] this research is certainly significant for the Gulf of Mexico Fishery Management Council and various oil producing states along the United States coastline. Louisiana commentators have remarked that the presence of several deep water structures (mainly oil and gas platforms) off the state's coast support an argument that Louisiana will be disproportionately affected by the implemented GMFMC plan.[52]

B. Necessity of Open Ocean Aquaculture

In 1997, attorneys for the Environmental Defense Fund remarked "as the [aquaculture] industry continues to grow, it will likely expand into the open ocean."[53] They also argued that conditions in the late 1990s - the high cost of engineering and building facilities able to withstand ocean storm conditions, the high cost of operating facilities far from shore, and the absence of a cohesive framework, would limit aquaculture's expansion into the ocean.[54]

The most prevalent stated reason for the need to expand aquaculture is the inability to supply the world's population with an adequate supply of marine food products given the stagnant rate of growth in capture fisheries and estimates of increased population.[55] In 1998, aquaculture experts predicted that total production will have reached between 35 million and 40 million tons of finfish, crustaceans, and mollusks by 2010.[56] "More than half a decade ahead of

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50. Draft Amendment, *supra* note 15, at 13.

51. *Id.*

52. For example, see Paula Devlin, *U.S. agency approves plan for Gulf fish farming*, The Times Picayune, September 3, 2009, *available at* http://www.nola.com/business/index.ssf/2009/09/us_agency_approves_plan_for_gu.html.

53. D. Douglas Hopkins, Rebecca J. Goldburg, & Andrea Marston, *An Environmental Critique of Government Regulations for Open Ocean Aquaculture*, 2 OCEAN & COASTAL L.J. 235, 236 (1996-1997).

54. *Id.*

55. *See generally*, FAO Report, *supra* note 18; Draft Amendment, *supra* note 15; NOAA Aquaculture Policy, *supra* note 6.

56. THE WORLD BANK, CHANGING THE FACE OF THE WATERS: THE PROMISE AND CHALLENGE OF SUSTAINABLE AQUACULTURE 1 (2007).

[those] projections," aquaculture production reached 45 million tons.[57] By 2004, aquaculture accounted for over forty percent of the global fish food supply; to compare, capture fisheries have averaged a growth rate of less than two percent.[58] Other common reasons given for the expansion of aquaculture into federal waters are: avoidance of state law regulation, avoidance of conflicts with other human uses of the sea surface, the ability to minimize regulatory compliance burdens because effluents are more readily disbursed,[59] and the ability to farm fish while maintaining the aesthetic look of a coastal area.[60]

More recently, advocates of open ocean aquaculture have cited a common theme to encourage commercial development of marine foods in federal waters: prevention of a race to the bottom for scarce environmental resources.[61] The prevention of a race to the bottom can encourage the United States to be (or not to be) involved in the production of aquaculture at all, *vis-à-vis* other nations. For example, China dominates the world's production of aquaculture. Furthermore, the prevailing view is that "China's economic planners view pollution as an inevitable or necessary byproduct of economic development. . . . hence, they are more interested in maintaining China's comparative advantage as the world's number one low-cost producer."[62] China's lower production costs, due to the lack of environmental regulatory compliance overhead, are thought to put domestic fisheries at a competitive disadvantage.

The perceived competitive disadvantage does not necessarily diminish if the United States decides to wade into the aquaculture market full force. Aquaculture firms will still undoubtedly be subject to a myriad of environmental laws: the Clean Water Act (most likely by National Pollution Discharge Elimination System point source permitting); the Endangered Species Act (if the installation,

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57. *Id.*

58. *Id.* at 15.

59. Hopkins, supra note 47.

60. Hope M. Babcock, *Grotius, Ocean Fishing Ranching, and the Public Trust Doctrine: Ride 'Em Charlie Tuna*, 26 STAN. ENVT'L L.J. 3, 24 (2007).

61. *See*, e.g., Thomas R. Head, III, *Fishy Business – Regulating Aquaculture Operations in the United States*, 18 NAT. RESOURCES & ENV'T 21 (2004).

62. Srini Sitaraman, *Regulating the Belching Dragon: Rule of Law, Politics of Enforcement, and Pollution Prevention in Post-Mao Industrial China*, 18 COLO. J. INT'L ENVTL. L. & POL'Y 267, 303 (2007). *See generally*, Thomas Friedman, Op-Ed, *Bring in the Green Cat*, N.Y. TIMES, Nov. 15, 2006; Pan Yue, *Growth vs. Ecological Calamity in China*, 23 NEW PERSP. QUARTERLY 54 (2006); Richard McGregor, *Pollution Fears Over China's Growth*, FIN. TIMES, Jan. 12, 2007.

creation, or maintenance of an aquaculture net, pen, or cage threatens an endangered species or its critical habitat); and the Marine Mammal Protection Act, to mention just three. For instance, the Congressional Research Service noted that even if the National Offshore Aquaculture Act passes, "[a]ny U.S. open ocean aquaculture enterprise will also face issues of how to compete in a global marketplace with nations whose aquaculture production costs are likely much lower."[63] Therefore the allure - for United States firms to invest in aquaculture operations and for ordinary consumers to purchase cheaper imported aquaculture products still exists. However, one could envision the ability of the United States aquaculture market to position itself strategically, for consumers who use their purchasing power in environmentally friendly ways, as the "clean" aquaculture industry.[64] According to Dan Swecker, founder of one of the first United States near-shore salmon farms, it may be too late to even mount a viable commercial industry because "[t]he industry went somewhere else already."[65]

Furthermore, assuming that the United States could eliminate, or at least mitigate to a profitable extent, competitive disadvantages, the finfish currently produced in an aquaculture environment, if expanded, would do little to ease the trade deficit. For example, Snapperfarm and Hukilau in Puerto Rico and Hawaii, respectively, each produce high-end sushi appropriate fish for sale in restaurants (amberjack and yellowtail (moi)). However, major seafood imports into the United States include shrimp, salmon, crabs, tilapia, tuna, and shellfish foods that are common seafood types available at grocery stores and mainstream restaurants.[66] Among those top six sea-

63. Eugene H. Buck & Rachel Borgatti, Congressional Research Service Report for Congress, *Open Ocean Aquaculture*, Dec. 13, 2004, *available at* assets.opencrs.com/rpts/RL32694_20041213.pdf.

64. *See generally*, Matthew Kirdahy, *Responsibility Pays*, FORBES (Nov. 13, 2007) *available at* http://www.forbes.com/leadership/2007/11/12/corporate-philanthropy-projects-lead-citizen-cx_mk_1112donors.html; Cait Murphy, *The Next Big Thing*, FORTUNE SMALL BUSINESS, June 4, 2003. For some companies that have the ability to produce U.S. aquaculture products for export, this marketing advantage may even prove fruitful in other countries. *See*, e.g., Vicki Silverman, United States Exhibitors Report Big Rise in Green Business (Apr. 26, 2004) (statement of the United States Department of State), *available at* http://america.gov/st/washfile-english/2004/April/20040426145651HVnamerevliso.html.

65. Querna, *supra* note 44, at 62.

66. FOOD & WATER WATCH, FISHY FARMS 8 (2007), *available at* http://www.foodandwaterwatch.org/fish/publications/reports/fishy-farms (collecting and summarizing data from *Fisheries of the United States 2006*, Office of Science and Technology, National Marine Fisheries Service, National Oceanic and Atmos-

food imports, the United States *exports* 71 percent of its domestic production.[67] Therefore, if United States aquaculture firms continue a pattern of cultivating "designer" fish, high scale production of these fish will do little to ease the import of frequently purchased consumer grade fish and shellfish.[68] Possibly more economically detrimental is the idea that commercial aquaculture in federal waters could *lower* the price for wild fish caught by domestic fishermen. While a lower market-based price for non-farmed fish caught by domestic fishermen may decrease the numbers of fish caught overall, it would certainly drive some domestic fishermen out of business.

Preventing a race to the bottom reinforces the benefit of a federalized aquaculture environment, as opposed to the current model, one that relies on regional fishery management councils. If all eight regional fishery management councils were subject to the same standards, one council could not attract more aquaculture business to the detriment of that localized area's watershed quality and the commercial interests of another region. The prevention of a race to the bottom *vis-à-vis* another geographic region has been the precursor of many of the federal government's overarching environmental laws, such as federal programs for the elimination of air and water pollution.[69]

III. AQUACULTURE'S ENVIRONMENTAL IMPACTS

> Aquaculture simultaneously poses the risks of transformation of entire wild ecosystems and the promise of managed aquatic ecosystems.[70]

Undoubtedly, aquaculture's expansion into the open ocean will lead to environmental problems. However, the *need to expand* aquaculture to the open ocean is causally connected to current nearshore environmental problems. In some areas, fish cannot be farmed near the coastline (in state-controlled waters) because of water quality problems caused by nonpoint and point source pollution

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pheric Administration (July 2007), *Imports and Exports of Fishery Product Annual Summary*, 2006, Fisheries Statistics Division, National Marine Fisheries Service, NOAA (2007)).

67. *Id.*

68. However, this would not be necessarily true of catfish, trout, and salmon, all current United States aquaculture products – this would depend on whether *those particular* heavily imported and exported finfish were to be produced on a broader scale.

69. For example, the Clean Water Act, 33 U.S.C.A. § 1251 *et seq.* (2006).

70. WORLD BANK, *supra* note 50, at 15.

including fertilizers, bacteria, pesticides, chemicals, acid deposition, sediment, and other possibly toxic pollutants.[71] Moreover, current near-shore aquaculture operations can damage water quality to the detriment of future operations. This may become an issue in Hawaii, as several more firms have applied for permits in areas near aquaculture operations owned by Hukilau and Kona Blue.[72]

The fact that aquaculture takes place in water, as opposed to agriculture, which takes place on land, represents both a challenge and benefit to aquaculture operations. Water operates as a natural filter, mitigating the effects of chemicals or pollutants. Additionally, one could argue that the vast quantity of moving ocean current means that the oceans are much more suitable to aquaculture than near-shore water bodies. However, because aquaculture takes place in moving water, a higher probability of "inadvertent transmission and spread of wastes, diseases, and genetic material, including introduced species and strains" exists.[73] Furthermore, "[a]quaculture poses a range of threats to aquatic biodiversity, and control over breeding and reproduction of farmed species is substantially more difficult than in the case of most livestock."[74]

Ecosystem degradation can occur because of solid waste production in the form of excess feed and fecal matter, which falls outside of a contained area and can be transferred to other wild fish. For example, cage salmon aquaculture operations in Scotland during the late 1990s generated 50,000 tons of untreated and contaminated waste, equivalent to the sewage waste of the population of up to three-quarters of Scotland's population.[75] A senior scientist with the conservation group Environmental Defense argues that growth in the offshore aquaculture industry close to the NOAA's goal of $5 billion per year would create as much nitrogen waste as that equivalent to "the untreated sewage of 17 million people."[76]

Additionally, fish farmers use antibiotics to control disease, pesticides to control parasites, and hormones to induce spawning and yield a larger catch.[77] In 1995, a herpes virus outbreak near several

71. *See* Babcock, *supra* note 54, at 23.

72. *See* Draft Amendment, *supra* note 15, at 13.

73. WORLD BANK, *supra* note 50, at 15.

74. *Id.*

75. Craig Emerson, *Aquaculture Impacts on the Environment* (1999), *available at* www.csa.com/discoveryguides/aquacult/overview.php.

76. Anne Mosness, An update to our report in April 2005: Ocean Aquaculture, June 2006, *available at* www.pccnaturalmarkets.com/SC/0606/SC0606-aquaculture.html.

77. Head, *supra* note 55, at 21.

tuna farms sideswiped the Australian aquaculture community, leaving behind a "sea of dead fish" - eventually killing 75 percent of the pilchards (a fish related to the herring) in the region.[78] Although there has been no conclusive proof of the source of the virus outbreak, members of Western Australia's Department of Fisheries believe that importing pilchards from "wherever the deal was cheap" led to the infestation.[79] Three years later, another attack wiped out most of the remaining pilchards.[80] Salmon anemia, although not harmful to humans, is currently killing off so many farmed salmon in Chile that the salmon farming industry, the third largest industry in the country, has laid off more than 1,000 workers.[81] The virus has been linked to widespread use of chemicals and antibiotics in fish pens.[82] According to one local Chilean fisherman, "the salmon companies 'are robbing [them of their] wealth' . . . [The companies] bring illnesses and then leave [the fishermen] with the problems."[83]

Closer to home, more and more species are being discovered off the coast of North America that carry a particular strain of hemorrhagic virus, as an expanding sardine population migrates north from Mexican waters in search of food.[84] According to one fish health observer, "opening more offshore farms in the United States will only open more opportunities for unregulated trade to spread disease."[85] Some ecologists question the proposition that penned fish are giving viruses to wild fish; some say that it is just as likely that wild fish may give viruses to penned fish.[86] One such marine ecologist, Donald Kent, served on the Marine Fisheries Advisory Committee by appointment in 2002; the Committee serves as an advisory board to the National Marine Fisheries Service on policies such as the proposed offshore farming legislation.[87] Moreover, Kent is currently president of the Hubbs Sea-World Research Institute, a California group that has applied for a research grant and permit

78. Rex Dalton, *Fishing for Trouble*, 431 NATURE 502, 503 (Sept. 30, 2004).
79. *Id.* at 503-04.
80. *Id.* at 503.
81. Alexei Barrionuevo, *Salmon Virus Indicts Chile's Fishing Methods*, N.Y. TIMES, March 27, 2008, at A6, *available at* http://www.nytimes.com/2008/03/27/world/americas/27salmon.html.
82. *See Id.*
83. *Id.*
84. Dalton, *supra* note 75, at 504.
85. *Id.*
86. *Id.*
87. *Id.*

from the state to conduct offshore aquaculture on an unused oil platform located in the Pacific Ocean.[88]

Fish may escape - possibly leaving "biological pollution" by altering native species composition and introducing foreign matter, such as antibiotics, into the native population.[89] For example, in 1999, federal officials in Maine estimated that only 500 Atlantic salmon with a native genetic makeup were left in the wild.[90] Aquaculturists that can genetically manipulate salmon through selective breeding with traits that are necessary to aquaculture at the expense of other characteristics can unintentionally breed traits that leave salmon less likely to survive in the wild upon escape and spawning.[91] In Everglades National Park, a release of blue tilapia in Florida has led to the loss of food, native habitat, and spawning areas for native species.[92]

Maintaining an aquaculture operation can itself lead to further depletion of the native fish population. Fish meal and fish oils from natural stocks are the main ingredients in artificial feed for carnivorous fish (such as salmon).[93] Between 1999 and 2003, the aquaculture industry's use of fishmeal and fish oil increased three-fold to three million tons and 800,000 tons, respectively.[94] In the late 1990s, it took three to five pounds of wild fish to produce only a pound of salmon; between 1985 and 1995, it took 36 million tons of wild fish to produce only 7.2 million tons of shrimp.[95] Currently, every two to six pounds of fish caught in the wild yield only one pound of cage raised fish.[96] Removing fish to create fish meal can lead to less food available for commercially valuable predatory fish and other animals dependent on marine life, such as seabirds, sea lions, and seals. Researchers at Snapperfarm have reported that using fishmeal "can be 3.7 times more efficient" than natural transformation.[97] The group is currently investigating the utilization of grain based feeds as opposed to fishmeal from the native population, given the "widely recognized" need to eliminate the use of fishmeal in aquaculture

88. *Id.*
89. Head, *supra* note 58, at 21.
90. Emerson, *supra* note 72, at 4.
91. *Id.*
92. *Id.* at 5.
93. *Id.* at 3.
94. Food & Water Watch, *supra* note 64, at 4.
95. *Id.*
96. *Id.* at 3.
97. Daniel Benetti, et al, *Can Offshore Aquaculture of Carnivorous Fish be Sustainable?*, WORLD AQUACULTURE, March 2006, 46.

feeds.[98] In addition to making less wild marine food available to other creatures, fishmeal, which can fall to the bottom of pens, cages, or nets, combines with similarly-released fish excrement to "suck oxygen out of the water, creating polluted 'dead zones.'"[99]

Current research regarding aquaculture operations at Snapperfarm has tentatively found that there were no "significant differences" in any water quality parameters measured in the areas surrounding underwater cages.[100] The company's president noted that currents carry over 500 million gallons of water through its pens each day, washing away sewage and excess food.[101] While Snapperfarm has benefitted from strong currents and limited aquaculture operations in its area, fish food and fecal matter still produce an "immense" amount of harmful nitrogen.[102] Furthermore, while some studies have shown negligible environmental impacts from current aquaculture activities, "these projects were conducted on small-scale operations mostly at low densities of fish, so their application to large-scale and/or concentrated marine fish farming is limited."[103]

IV. PREVIOUS ATTEMPTS UNDER EXISTING LAW TO STOP AQUACULTURE PROJECTS

A. Existing Federal Laws Impacting Aquaculture

As previously mentioned, one of the impetuses for the recommendation of and congressional support for the National Offshore Aquaculture Act has been critique of the disjointed federal regulation affecting aquaculture.[104] The primary federal statute governing aquaculture activities is the Magnuson-Stevens Act,[105] which regulates

98. *Id.*

99. *See* Querna, *supra* note 49, at 62. Biologist Theirry Chopin has argued that a way to mitigate this problem would be to grow symbiotic species near one another. *Id.* For example, growing mussels, salmon, and seaweed in close proximity produces a natural solution to excess waste - because mussels and seaweed naturally clean up salmon waste. *Id.*

100. Benetti, *supra* note 97, at 44.

101. Querna, *supra* note 49, at 62.

102. *See* Helvarg, *supra* note 17, at 2.

103. MARINE AQUACULTURE TASK FORCE, *SUSTAINABLE MARINE AQUACULTURE: FULFILLING THE PROMISE; MANAGING RISKS*, 2 (Jan. 2007), *available at* http://www.pewtrusts.org. *See also*, Food & Water Watch, *supra* note 64, at 6.

104. *See* supra, note 11. *See also*, MARINE AQUACULTURE TASK FORCE, *supra* note 103, at 24-26; Babcock, *supra* note 60, at 25-26.

105. 16 U.S.C.A. §§ 1801-1883 (West 2007).

harvesting and possession of marine fish in federal waters. The Magnuson-Stevens Act governs the Gulf of Mexico Fishery Management Council's actions to maintain a sustainable yield in the Gulf of Mexico. However, under the Magnuson-Stevens Act, an exempted fishing permit from the National Oceanic and Atmospheric Administration (and NMFS) is required to engage in research-oriented aquaculture. An exempted fishing permit only covers research aquaculture operations; no permitting scheme exists for commercial aquaculture.

Several other federal statutes impact aquaculture activities. The Clean Water Act (CWA)[106] prohibits the discharge of pollutants into navigable waters from a point source without a National Pollution Discharge Elimination System (NPDES) permit.[107] The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[108] regulates the labeling and use of pesticides; EPA recently amended FIFRA regulations to exempt aquaculture pesticides that can affect water quality.[109] The 1899 Rivers and Harbors Act (RHA)[110] controls the siting of structures that affect navigable waters (such as net pens or cages) as overseen by the Army Corps of Engineers. The Endangered Species Act (ESA)[111] protects federally listed endangered species and their and other species' critical habitats (including marine species). While all of these laws affect aquaculture, "none was really crafted with the regulation of marine aquaculture in mind."[112]

B. State Aquaculture Laws

Several states have regulations concerning fish farming in state-controlled near-shore waters. For example, the Louisiana Aquaculture Development Act[113] provides a statewide regulatory framework "for the orderly development and maintenance of a modern aquacultural segment of Louisiana's agriculture industry and for the promotion of aquaculture and aquacultural products."[114] The Act

106. 33 U.S.C.A. §§ 1251-1387 (West 2006).
107. *Id.* at § 1342.
108. 7 U.S.C.A. §§ 136-136y (West 2007).
109. 70 Fed.Reg. §§ 5093, 5098 (West 2005). The regulation applies to "producers of farm raised finfish (e.g., catfish, trout, goldfish, tropical fish, minnows) and/or hatching fish of any kind."
110. 33 U.S.C.A. § 403 (West 2007).
111. 16 U.S.C.A. §§ 1531 *et seq.* (West 2007).
112. Report of the Marine Aquaculture Task Force, *supra* note 103, at 24.
113. LA. REV. STAT. ANN. §§ 3:559.1 *et seq.* (West 2007).
114. *Id.* § 559.2(C).

created the Louisiana Aquaculture Coordinating Council, a group of commercial, governmental, and environmental representatives.[115] The Louisiana Aquaculture Coordinating Council recommends which marine species would be best suited for aquaculture production in state-controlled waters and advises the Commissioner for the Department of Agriculture and Forestry about possible permitting requirements.[116] The Commissioner has the power to issue permits and licenses for near-shore aquaculture operations and to institute actions for fines and penalties for permitting violations.[117] The permitting scheme provides for yearly licenses for finfish and crawfish producers; however, specific bass species are excluded.[118] After Hurricane Katrina, the United States Department of Agriculture awarded $4.5 million to aquaculture producers affected by the storm through the Aquaculture Bulk Grant Program.[119]

C. Previous Legal Challenges to Aquaculture Operations

Given the myriad of federal and state programs related to individual components of water quality that can impact fishing operations (i.e., polluted waterways, agricultural runoff, pesticide use, etc.), interested parties have turned to the courts when the regulatory structure fails. Thus far, the most successful challenges to state, regulated aquaculture activities have been through the use of the Clean Water Act. In *United States Public Interest Research Group v. Atlantic Salmon of Maine, LLC,* the district court[120] and the First Circuit Court of Appeals[121] found that environmental hazards caused by a local salmon farm justified both an injunction from operating until the company got a valid NPDES permit and a ban on the use of non-native salmon species. Atlantic Salmon of Maine (ASM) obtained an aquaculture lease from the state and an Army Corps of Engineers permit under the Rivers and Harbors Act, but not a Clean Water

115. *Id.* § 559.4.
116. *Id.* § 559.6.
117. *Id.* § 559.6 B(4) & (7).
118. Ca.Rev.Stat.Aqu. 3:559.8, .14.
119. Louisiana Department of Agriculture & Forestry: *Aquaculture Producers to Get $4.5 Million in Disaster Funds,* 2007 http://www.ldaf.state.la.us/portal/News/PressReleaseCurrent/tabid/92/ItemId/1156/Default.aspx (last visited Mar. 27, 2010).
120. United States Public Interest Research Group v. Atlantic Salmon of Maine, 257 F.Supp.2d 407, 435-36 (D.C. Me 2003).
121. 339 F.3d 23, 35 (1st Cir. 2003).

Act NPDES permit.[122] The company operated five salmon farms, all utilizing net pens moored to the sea floor.[123] Salmon were harvested for the local market after eighteen to twenty-four months.[124]

The district court found several environmental problems with the company's operation: discharge into the marine environment of a copper-laced chemical used to treat the nets; discharge of pharmaceutical pigments present in the salmon feed; the presence of bacterial kidney disease and virbio; discharge of the chemicals used to treat salmon bacterial infection and sea lice; release of salmon feces and fish waste at least thirty days per year; and escapee fish that altered the genetic disposition of native fish in the area.[125]

Years after the company began operations, and on account of an "intent to sue" letter sent to Maine's EPA's Region One office, the EPA informed the company it would be required to obtain an NPDES permit because the farms constituted Concentrated Aquatic Animal Production Facilities under federal regulation and were therefore point sources.[126] ASM did not send in any of the requested information on any of the farms. In 1993, ASM wrote EPA asking for a "letter of assurance" that the farms could operate without an NPDES permit.[127] After receiving the letter, EPA notified the Public Interest Research Group that EPA "had not considered sea farm discharges to be a significant environmental concern, falling into the 'minor' permit category that EPA could not address due to resource constraints."[128]

The Court found that escaped farmed salmon were pollutants under the CWA, insofar as escapees "can negatively affect the endangered wild salmon by spreading pathogens and parasites and by competing for food, habitat, maters, and spawning sites."[129] The

122. *Atlantic Salmon*, 257 F.Supp.2d at 417.

123. *Id.* at 410.

124. *Id.*

125. *Id.* at 410-12.

126. *Id.* at 414-15. Under 40 C.F.R. § 122.24(b) (West 2000), Concentrated Aquatic Animal Production facilities are point sources subject to the NPDES permitting program. A fish farm can be considered a CAAPF either because it meets certain production criteria, or because EPA determines, through a case-by-case evaluation, the facility is a "significant contributor of pollution to waters of the United States." *Id.* §122.24(c)(1).

127. *Atlantic Salmon*, 257 F.Supp.2d. at 415. Delegation to the state of Maine for the NPDES program did not occur until 2001. *Id.*

128. *Id.* at 418. A portion of the case concerns the company's adherence to the Maine Finfish Aquaculture Monitoring Program, created in 1992. *Id.* at 417. This portion of the case is not addressed by the author.

129. *Id.* at 420.

introduction of non-native species posed such a problem for the region that the EPA determined in 2000 that a valid NPDES permit must prohibit non-North American salmon strains.[130] Despite the myriad of environmental harms done by ASM, the Court found that the company had attempted to mitigate some of the "negative impacts" of its operations, some at considerable costs.[131] Furthermore, the Court placed much blame where it rightfully belonged - at the foot of the state and federal agencies involved in the aquaculture industry.[132] The Court noted that "regulatory inertia" had given ASM "a free pass to continue their heedless despoiling of the environment."[133]

In order to rectify the damage, the court issued a permanent injunction against the use of non-North American strains of Atlantic salmon and an injunction against operations until the company obtained the requisite NPDES permit.[134] The First Circuit upheld the injunction irrespective of the fact that Maine issued ASM a general permit for salmon aquaculture that would *permit* restocking one of ASM's farms with non-native salmon.[135]

As *Atlantic Salmon* demonstrates, the Clean Water Act could potentially be a powerful tool to remediate and mitigate environmental harms caused by offshore aquaculture. However, one conclusion of the court, that pesticides were pollutants from a point source subject to the NPDES program, can be undercut in future cases by recent EPA action concerning the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The EPA recently added regulations to FIFRA that would exempt pesticides used in aquaculture from the proscriptions of the Clean Water Act. In 2005, the EPA issued a rule that "exclude[s] applications of pesticides to waters of the United States [from the Clean Water Act] consistent with all relevant requirements under FIFRA" in two cases:

> 1) the application of pesticides 'directly to' waters of the United States in order to control pests; and
>
> 2) the application of pesticides to control pests that are present over waters of the United States, including near such waters, that results in a

130. *Atlantic Salmon*, 257 F.Supp.2d. at 421n:6. By that time, Maine operated its own NPDES permit system. *See supra*, note 127.
131. *Id.* at 431.
132. *Id.* at 430-31.
133. *Id.* at 431.
134. *Id.* at 434-35.
135. *Atlantic Salmon*, 339 F.3d at 30-31.

> portion of the pesticides being deposited to waters of the United States.[136]

The regulation specifically affects farming and fishery hatcheries that produce farm raised finfish, including catfish, trout, goldfish and any hatching fish of any kind.[137] According to the EPA, "these types of applications do not require NPDES permits under the Clean Water Act if the pesticides are applied consistent with all relevant requirements under FIFRA (*i.e.*, those relevant to protecting water quality)."[138] FIFRA, however, is not a statute concerned with water quality; unarguably, the predominant federal statute concerning water quality is the Clean Water Act. Therefore, application of this FIFRA regulation would preclude a court from enjoining discharges of pesticides from a fish farm.

In *Assoc. to Protect Hammersley, Eld, and Totten Inlets v. Taylor Resources, Inc.*, the Ninth Circuit found that the release of naturally occurring materials from a mussel harvesting facility, which enter Puget Sound, were not discharges in violation of the CWA.[139] The critical distinction between these two cases is that Taylor Resources "does not add any fish food or chemicals to the water; the mussels are nurtured exclusively by the nutrients found naturally in the waters of Puget Sound."[140] Taylor Resources attaches mussel seeds to suspension ropes that are anchored to the sea floor.[141] The ropes are then surrounded by mesh netting that protects the mussels from predators; no chemicals or fish food is added to the water and the mussels develop naturally.[142] The court found no violation even though mussel byproduct and shell were released from the facility, adding "something" to Puget Sound.[143]

Thus, EPA's mandate is clear: at this point, the only effective way to control near-shore marine aquaculture on the federal level, the Clean Water Act, would not now apply to pesticides released into fish farm waters. Given that the Clean Water Act may no longer operate as an effective enforcement mechanism for commercial aquatic facilities, *something* should be done to regulate the expansion of aquaculture.

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136. Application of Pesticides to Waters of the United States in Compliance with FIFRA, 70 Fed. Reg. 5093, 5097-98 (Jan. 25, 2005).
137. *Id.* § 5094.
138. *Id.* § 5098.
139. 299 F.3d 1007, 1019 (9th Cir. 2002).
140. *Id.* at 1010.
141. *Id.*
142. *Id.*
143. *Id.*

V. CONCURRENT EFFORTS TO RESOLVE THE CONFLICT

Given the state of the law, both regional fishery associations and the federal government recognize the need to regulate aquaculture expanding into the open ocean. Each group has proposed a solution; the solutions, however, are inconsistent. Both the Gulf of Mexico Fishery Management Council and the federal government have proposed a regulatory solution that would allow commercial aquaculture in federal Gulf of Mexico waters. NOAA has announced it will neither approve nor disapprove of the GMFMC's plan to begin aquaculture permitting. NOAA's failure to approve or disapprove of the plan will likely ensure the exact opposite of its stated objection - a consistent federal programming scheme.

A. Action by the Gulf of Mexico Fishery Management Council

The Gulf of Mexico Fishery Management Council announced its intent to amend its fishery management plans (FMPs) covering red drum, reef fish, and stone crab to allow commercial aquaculture in the Gulf.[144] The Council consists of seventeen voting members, many of whom are chosen by the United States Secretary of Commerce upon nomination by the governor of each participant state.[145] Other members include the principal state official with marine fishery responsibility and the NMFS regional director for the geographic area.[146] Each voting member, several of whom represent commercial and recreational fishing interests, serves a three year term and can only serve three consecutive terms.[147] The Council is required under the Magnuson-Stevens Act to prepare and submit to the Secretary a fishery management plan for each fishery under its authority that requires conservation and management, and amendments to each such plan.[148] Public hearings are required before amendments to fishery management plans can be approved by the Secretary.[149] A fishery management plan has to specify, among other things, the number of catch allowable among any given regulated species in order to prevent overfishing and allocate that number of catch between commercial and recreational fishing interests.[150]

144. *See* Draft Amendment, *supra* note 15.
145. 16 U.S.C.A. § 1852(a)(1)(E), (b)(2)(c) (2006).
146. *Id.* § (b)(1).
147. *Id.* § (b)(2)(E)(3).
148. *Id.* § (h)(1).
149. *Id.* § (h)(3).
150. 16 U.S.C. § 1853 (2006).

The Council has to amend its FMPs to include commercial aquaculture based on an opinion letter of the NOAA's General Counsel that aquaculture constitutes "fishing" as defined in the Magnuson-Stevens Act.[151] Since the Council can control "fishing" operations only through a fishery management plan, the plans administered by the Council must be amended.[152] The Council acknowledges that an increase in domestic aquaculture production may not lessen global marketplace competition for aquaculture products (and presumably, its harmful economic impacts on Gulf fishermen).[153] However, the Council intends to go forward with its plan to create a regional permitting process for commercial aquaculture "to increase the maximum sustainable yield and optimum yield of federal fisheries in the Gulf of Mexico by supplementing the harvest of wild caught species with cultured product."[154] The permitting scheme would require a National Marine Fisheries Service permit to operate a facility in the Gulf EEZ.[155]

Four alternatives were offered as to the types of species available for possible permitting. Those options include:

> 1) an option to raise non-native species;
>
> 2) an option to raise most species currently managed by the Council (excluding spiny lobster, stone crab, corals, and shrimp);
>
> 3) an option to raise most species currently managed by the Council plus spiny lobster and stone crab; and
>
> 4) an option to allow aquaculture of all marine species currently managed by the Council except shrimp and coral, including *highly migratory species*.[156] According to the Council, most reef fish could be raised in aquaculture systems, including cobia, mutton snapper, amberjack, red snapper, and red drum.[157]

Permit durations under the Draft Amendment can range from one year to indefinitely, although the current "preferred" alternative

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151. The Council gets this interpretation of "fishing" under the MSA from a legal opinion by General Counsel for the NOAA. Draft Amendment, *supra* note 15, at 6. "Fishing," under the MSA is defined as "(A) the catching, taking, or harvesting of fish; (B) the attempted catching, taking, or harvesting of fish; (C) any other activity which can reasonably be expected to result in the catching, taking, or harvesting of fish; or (D) any operations at sea in support of, or in preparation for, any activity described in subparagraphs (A) through (C)." 16 U.S.C. § 1802(16)(2006).

152. Draft Amendment, *supra* note 15, at 6.

153. *Id.* at xiv.

154. *Id.* at x.

155. *Id.* at 1.

156. *Id.* at xvi (emphasis added).

157. Draft Amendment, *supra* note 15, at 73.

is one that is effective for ten years, and renewable in five year periods thereafter.[158] This "preferred" alternative would limit aquaculture operations to cages and nets for rearing native Gulf species such as red snapper or grouper, and would not allow federal water offshore farming facilities for shrimp.[159] The "preferred" alternative would also require an assurance bond payable to the Council, an operational plan to manage genetic diversity and aquatic health, and environmental monitoring.[160] The National Marine Fisheries Service would be responsible for reviewing each request for a commercial aquaculture site on a case-by-case basis.[161]

Louisiana created a Platform for Marine Aquaculture Task Force "to assess the economic feasibility, environmental impact, and legal/regulatory considerations of utilizing offshore oil and gas platforms for culturing marine organisms in the Gulf."[162] The task force found that "it is reported that the central [Gulf of Mexico] shelf contains the highest density of oil and gas production platforms in the world. Therefore, it is practical to consider that the use of existing GOM production platforms could prove beneficial in expediting the development of a mariculture [aquaculture] industry in Louisiana."[163]

Currently, no permit applicants are seeking to construct offshore aquaculture operations in the Gulf EEZ.[164] However, commercial aquaculturists are seeking to utilize offshore oil platforms for their operations in other geographic areas. In 2003, the Hubbs-Sea World Research Institute leased part of an oil platform off the coast of California to conduct a feasibility study of the development of marine aquaculture using offshore oil platforms.[165] Also, in the early 1990s, scientists at Texas Sea Grant used an Occidental Petroleum

158. *Id.* at 2.

159. Chris Kirkham, *Fish Farm Plans Under Scrutiny*, THE TIMES PICAYUNE (April 6, 2008). *See also*, Draft Amendment, *supra* note 15, at xvii.

160. *Id.* at xvi.

161. *Id.* at xvii.

162. *Id.* at 7. The PMATF was created following the passage of Louisiana House Concurrent Resolution No. 176 (HCR 176) (2004). Louisiana Coastal Management Program, ASSESMENT & STRATEGY, 64, *available at* http://www.dnr.louisiana.gov/CRM/COASTMGT/cup/noticer/spn2006.04.01/20060303.draft.pdf

163. Louisiana Platforms for Mariculture Task Force, FINAL REPORT OF FINDINGS AND RECOMMENDATIONS TO THE LOUISIANA LEGISLATURE AND GOVERNOR, 10 (2005), *available at* http://dnr.louisiana.gov/mariculture/final_report.pdf.

164. Draft Amendment, *supra* note 15, at 14.

165. *Id.* at 13. This project has currently not been permitted, possibly because Crystal Energy, another lessee of the platform, began using it as an LNG import and regasificaiton facility. *Id.* at 14.

Corp. platform to grow redfish; the cages were damaged, leading to escaped fish, after a severe Gulf storm.[166] Furthermore, the efforts to raise the redfish cost $22 per pound; the fish themselves were only worth $3.50 per pound on the open market.[167]

This partnership between oil companies and aquaculture companies has some troubling undertones. The projects operating on oil platforms "begin" as research projects; Hubbs Sea-World has eventual plans to turn its project into a commercial venture "using millions of dollars from fish sales to support the facility and its research."[168] Oil companies have a vested interest - for instance, Chevron, the lesser of the Hubbs-Sea World platform, funded the institute's start up costs, and offered $10 million to run the institute for three years, hopefully avoiding the "substantial expense" of removing the oil platform completely.[169] A 500-acre, four platform oil and gas complex off the coast of Texas was approved for conversion from an oil site to an aquaculture site in 1999; since then (and after litigation), the Gulf Marine Institute of Technology has announced that it has all the permitting required to begin its production facility. Devon Energy Corporation (formally Seagull Energy) donated the platform with a $5 million value to the company, which agreed to dismantle the platform at an estimated cost of $2.5 million once it ceases its aquaculture operation.[170]

Oil companies are looking out for their best economic interests by shifting the cost of removing abandoned platforms to another potentially responsible party. However, research-oriented offshore aquaculture is *heavily* subsidized by the federal government. For example, in the Gulf of Mexico alone, Congress distributed more than $300,000 to fund research projects.[171] Since 1999, the United States Department of Commerce has granted close to $3 million to companies involved with offshore aquaculture and funded over $9

166. *Id.*

167. *Id.*

168. Dalton, *supra* note 78, at 502.

169. *Id.*

170. Gulf of Mexico Fishery Management Council, *Economic Impacts of Gulf Aquaculture Amendment*, n.4, *available at* www.gulfcouncil.org.

171. Food & Water Watch, *Offshore Aquaculture Kept Affloat with Government Funding*, 9 (2007) *available at* http://www.foodandwaterwatch.org/fish/fish-farming/offshore/problems/Offshore_aquaculture_kept_afloat_ with_government_ funding/ (detailing the amount and type of federal grant money devoted to aquaculture research programs over the past several years in all areas of the country in which near-shore aquaculture is currently practiced).

million in research.[172] The merging of oil interests and commercial aquaculture fishing interests, especially in areas in which the coastline has been undeniably affected by oil exploration and production activity, should be carefully scrutinized. Further, start-up expenses for commercial aquaculture will be considerable; federal subsidies for aquaculture may well create "Big Aquaculture" much like "Big Agriculture."

The Council's plan has been met with vocal opposition.[173] Food and Water Watch, a non-profit consumer advocacy group that has submitted several public comments to the proposed amendment, urged the GMFMC to slow down its current pace to finalize the plan.[174] Food and Water Watch stated that to push a measure through so quickly was "a failure of the fisheries management system and a flagrant disservice to the people whom [the Council] represents as a trustee of the Nation's marine fisheries resources."[175]

B. Proposed New Federal Legislation

Comments on the Draft Amendment indicated the main concern was one of the environmental effects of having any open ocean aquaculture in the Gulf at all. However, few, if any, have discussed what possible enactment of the National Offshore Aquaculture Act[176] would do to the Council's proposed plan. The Act (introduced by Rep. Nick Rahall (D. WV)) would establish an all-encompassing federal regulatory system for offshore aquaculture in the United States EEZ.[177] The Act follows on the heels of a similar attempt to introduce a regulatory program in 2005. The program would include financial support to an offshore aquaculture industry, the establishment of a permitting process, and research and development sup-

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172. *Id.*

173. The Mangrove Action Project, Letter to Gulf of Mexico Fishery Management Council on Offshore Aquaculture (Oct. 2007) www.mangroveactionproject.org/news/current_headlines/letter-to-gulf-of-mexico-fishing-management-council-on-offshore-Aquaculture; Food & Water Watch memo regarding the public hearing draft amendment (Jan. 2008) *available at* www.foodandwaterwatch.org.

174. Press Release, Food and Water Watch, Gulf Council Ocean Fish Farming Plan Illegal (Jan. 17, 2008) *available at* http://www.foodandwaterwatch.org/press/press-releases/gulf-council-ocean-fish-farming-plan-illegal/j. Press Release, Food and Water Watch, Bad Ocean Fish Farming Plan Blocked (Jan. 31, 2008) *available at* http://foodandwaterwatch.org/press/press-releases/bad-ocean-fish-farming-plan-blocked/.

175. Food and Water Watch memo, *supra* note 173, at 2.

176. National Offshore Aquaculture Act of 2007, H.R. 2010, 110th Cong. (2007).

177. *See Id.* at § 2.

port.[178] Legislators are currently debating the Act in the House Subcommittee on Fisheries, Wildlife, and Oceans and the Senate Committee on Science, Commerce, and Transportation.[179]

The Act would authorize the Secretary of Commerce to issue offshore aquaculture permits and establish environmental requirements for commercial aquaculture activities.[180] Permits issued by the Secretary would exempt offshore facilities from regional fishery management council fishing regulations that restrict size, season, and harvest.[181] Such permits would be for twenty years (renewable in up to twenty year increments) and would specify the location of the commercial facility and the species to be grown.[182] The permitting process would require consultation with the regional fishery management councils established by the Magnuson-Stevens Act and adherence to environmental standards designed to safeguard genetic resources and preserve marine ecosystems.[183] In a departure from an option of the currently proposed Gulf of Mexico Fishery Management Council plan, however, the Act would require "that marine species propagated and reared through offshore aquaculture be species native to the geographic region unless a scientific risk analysis shows that the risk of harm from the offshore culture of non-indigenous or genetically modified marine species is negligible or can be effectively mitigated."[184] Under the Act, if any State elected to "opt-out" of offshore aquaculture, no facilities could be permitted within twelve miles of that state's coastline.[185]

According to Wayne Swingle, the former Director of the Gulf of Mexico Council,

> [t]he Congressional act when passed would supersede the amendment rule. The act would likely apply to all the finfish and most invertebrates, whereas the amendment will apply to only the fish managed by the

178. *Id.*

179. National Offshore Aquaculture Act of 2007, S. 1609, 110th Cong. (2007) (last major subcommittee hearings held 7/12/2007).

180. U.S. DEP'T OF COMM, NOAA Aquaculture Program, *Highlights of the 2007 National Offshore Aquaculture Act*, March 12, 2007, *available at* www.aquaculture.noaa.gov. The Act may be dead in the 110th Congress, but the author anticipates another re-introduction.

181. *Id.*

182. *Id.*

183. H.R. 2010 at § 4(a) & (d)(4).

184. *Id.* at § (a)(4)(E).

185. Highlights, *supra* note 180.

> council, i.e., about 70 species. All firms operating under the amendment likely would apply for permits issued under the act.[186]

The possibility of "superseding" raises some questions. As it currently stands, the 2007 Act contains no provision "grandfathering" in permits possibly issued by the Gulf of Mexico Council or any other regional fishery council. The Council's Draft Amendment states that it wants to implement its permitting plan because the national legislation is currently only in debate, and even if enacted into law in the near future, would take several years to implement.[187] However, a question may arise as to what "interest" a facility operator would have in continuing a regional permit, if for instance, a federal permit over the same facility were subsequently denied.[188] For example, if the Gulf Council's plan passes, and a commercial facility is granted a 10 year permit under the "preferred" alternative, and then the same company is denied a federal permit if the Act passes, such company could make an arguable takings claim. A permit from the Council could contain a disclaimer stating that the holder has no vested property right; however, the likelihood that a company would invest significant financial and physical resources into a facility requiring a permit, when such permit could be easily superseded, is slim.

Furthermore, the Act purports to exclude "offshore aquaculture conducted in accordance with permits issued pursuant to this Act" from the definition of "fishing" in the Magnuson-Stevens Act.[189] This deliberate exclusion highlights an interesting issue. According to the Gulf Council, it has the authority to amend its fishery management plan to create a permitting program for open-ocean aquaculture *because* "fishing" as defined in the Magnuson-Stevens Act includes aquaculture.[190] The Act, however, would exclude aquaculture from the definition of "fishing," which could indicate that Congress did not intend, in passing the Magnuson-Stevens Act, for

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186. Email from Wayne Swingle, former Executive Director, Gulf of Mexico Fishery Management Council (March 24, 2008) (on file with author).

187. Draft Amendment, *supra* note 15, at 16-17.

188. This mirrors problems that have arisen on the strictly federal level concerning the bifurcation of construction permits from operating permits. It seemed unlikely in a case where a private entity spends millions of dollars to construct a facility, with a permit from the United States government, that the United States would deny that facility an operating permit. In this situation, however, the "permit-granting" interests are both federal government and "a quasi-federal agency," which likely have divergent interests.

189. H.R. 2010 at § (4)(d)(4).

190. *See supra*, note 150 and accompanying text.

the definition of "fishing" to include commercial open-ocean aquaculture.

To the extent "fishing" does include aquaculture upon passage of the Act, from what source would the GMFMC derive its authority? "Fishing," as defined by the Magnuson-Stevens Act, includes the catching, taking, or harvesting of fish or an attempt to take, catch, or harvest fish. Irrespective of the NOAA's assertion (through its General Counsel) that "fishing" includes open-ocean aquaculture; the Council may not have the authority to amend its fishery management plan to provide for a region-wide permitting program in the Gulf of Mexico EEZ. In either case, failure to pass the Act should spark a debate about whether aquaculture is actually included in the definition of the term "fishing." Congress's deliberate exclusion of aquaculture from "fishing" in the 2007 Act could provide evidence in a legal action challenging the Council's statutory authority. One could argue that "harvesting" of fish includes commercial aquaculture. However, such a decision should be left to the courts or to Congress. Even though the construction of the term "harvesting" could reasonably include commercial aquaculture and the NOAA is entitled to a certain amount of deference in construing the statute it is charged with administering, commercial aquaculture will take such a large effort and expenditure of money and resources that any federally supported aquaculture actions should be more carefully considered by Congress.

NOAA, however, has stated it believes current federal laws provide adequate authority to regulate aquaculture. Interestingly, NOAA took this position while simultaneously refusing to approve or disapprove of the GMFMC's plan, stating,

> [w]e believe that permitting plans of this scope should be governed by a national policy. In the absence of a consistent national policy, it was not prudent to take action on the plan at this time.[191]

NOAA's failure to take action does the exact opposite of its stated intention to develop a consistent national policy; it instead ensures that the development of aquaculture in federal waters will be regionally fragmented.

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191. Press Release, National Aquaculture and Atmospheric Administration, NOAA to Pursue National Policy for Sustainable Marine Aquaculture, Press Release, National Aquaculture and Atmospheric Administration (Sept. 3, 2009).

VI. CONCLUSION

A clear conflict exists between the interests of the Gulf of Mexico Fishery Management Council on the one hand, and the federal government on the other. Furthermore, although the evidence is mixed, one could easily find that current technology is not adept enough to adequately mitigate the possible environmental damage from open ocean aquaculture, especially in the Gulf of Mexico. Both the NOAA and the governing bodies of some coastal areas, however, are intent on pushing forward with an open-ocean aquaculture plan. At this point, the only realistic option is not to stop both plans (which is likely impossible), but to enact the plan that best serves the goals of environmental conservation of scarce resources while opening the ocean for commercial purposes. Because NOAA has chosen to not approve or disapprove of the GMFMC Plan, recourse to the courts may be needed to determine precisely what regulatory authority NOAA has to regulate commercial aquaculture in federal waters. Congress could also effectively end the GMFMC's commercial aquaculture plan by specifying that "fishing" as defined in the Magnuson-Stevens Act, does not include commercial aquaculture. At the moment, the best plan seems to be a comprehensive federal regulatory scheme. Such a scheme would safeguard the interests of all coastal areas, by preventing a race to the bottom for commercially favorable environmental laws.

What is it about the ocean that seems to inspire such appreciation? It may be that unlike land, one cannot stake a clear marker in the ocean. For the most part, one cannot mark "her territory" in the ocean, as the United States has done on land, in foreign nations, and even on the moon. It is the haven of mysterious creatures untamable or commercialized by man, at least, until now.

KILLING US SWEETLY: HOW TO TAKE INDUSTRY OUT OF THE FDA

Jason Iuliano[*]

For more than a century, the Food and Drug Administration has claimed to protect the public health. During that time, it has actually been placing corporate profits above consumer safety. Nowhere is this corruption more evident than in the approval of artificial sweeteners. FDA leaders' close ties to the very industry they were supposed to be regulating present a startling picture. Ignoring warnings from both independent scientists and their own review panels, FDA decision makers let greed guide their actions. They approved carcinogenic sweeteners such as saccharin, aspartame, and sucralose while simultaneously banning the natural herb stevia because it would cut into industry profits. This Article proposes two reforms that can end these corrupt practices and take industry out of the FDA. By strengthening conflict of interest regulations and preventing companies from participating in safety trials, the FDA will be able to gain the independence it needs in order to regulate the food and drug industries.

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INTRODUCTION

It is a beautiful summer day. As you cruise down the highway, the sun shines through the windshield, warming your skin. A sign appears in the distance. It's too far away to read, but you know what it says anyway: "Beach 10 miles." You can already see the welcoming white sand and feel the refreshing ocean water. Today promises to be amazing. It's a shame that the next two hours will be the scariest moments of your life.

Just as you lean over to turn on your favorite radio station, everything flips 180 degrees. The ground and sky have traded places. Your vision indicates that your car is flying upside down through the air. You clench your eyes shut and brace for the expected impact with the ground. After a couple of terrifying, but uneventful, seconds, you risk a glance. Surprisingly, your car is gently coasting down the road. A thankful sigh escapes your lips. This relief, however, is short-lived as you notice an even more chilling problem. Although all the other cars are still in their lanes, they appear to be driving on the ceiling. Adding to the confusion, the sun is shining up from the floor. It takes a moment to come to this realization, but you know that, somehow, your vision has become inverted.

Panicked, you slam the brakes and turn the wheel towards the shoulder of the road. The car comes to a stop right next to the beach sign. Just another ten miles. You pull out your cell phone and dial 911. In the blink of an eye, your entire world has literally turned upside down.

Fifteen minutes later, the emergency room doctors are running a series of tests. An hour passes; the results come back negative. Your mother has arrived and is standing at the bedside sobbing. Seemingly, in defiance of gravity, a tear slips across her cheek and falls up.

Yet another doctor approaches. He asks an odd question. Do you drink diet soda? You grumble inwardly, thinking that there are more pressing matters at hand than your beverage preferences. Nonetheless, you tell the doctor that you enjoy diet soda from time to time and happened to drink a few cans this past week. The doctor nods knowingly and informs you that the aspartame in those diet

sodas is likely producing this frightening experience. He has had a number of other patients with similar symptoms, and, in those cases, artificial sweeteners have been linked as the cause. A short while later, your vision returns to normal, but you vow never to drink diet soda again.[1]

Many people's first reaction is that artificial sweeteners could not be this dangerous. After all, they are FDA-approved, and the government would not let a harmful chemical enter the food supply. Unfortunately, their faith rests on a presumption that no longer holds true.

If only there were an impartial government administration that regulated the food and drug industries, that agency surely would have protected the American people from such a toxic substance. At one time, the Food and Drug Administration (FDA) filled this role, serving as the much needed corporate watchdog, but now, it is nothing more than a corporate lapdog. Today, any company with enough money can buy approval for even the most dangerous products.

There is also a disturbing corollary to this problem. These same powerful companies can prevent competing products from getting FDA approval.[2] Often, the products most easily targeted are safe, natural substances that cannot be patented. When a new, healthy product is submitted to the FDA without a large corporate backer, approval is anything but certain. If a wealthy corporation fears that this new product will cut into its profit margin, it can put

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1. *See* JOSEPH MERCOLA, SWEET DECEPTION: WHY SPLENDA, NUTRASWEET, AND THE FDA MAY BE HAZARDOUS TO YOUR HEALTH 36 (2006) (describing a similar experience); *see also* HYMAN JACK ROBERTS, ASPARTAME DISEASE: AN IGNORED EPIDEMIC 68 (2001) (Roberts clinically observed 1200 patients who had adverse reactions to aspartame. More than 500 patients experienced vision problems, and 27 of those suffered blindness in one or both eyes.).

2. *See Delays in the FDA's Food Additive Petition Process and GRAS Affirmation Process: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong., at 78 (1995) (statement of Robert C. Gelardi, Executive Vice President, Calorie Control Council) (noting that "the careful timing of their submissions can hold up a review numerous times just short of approval"); *id.* at 90-91 (describing how anonymous submissions are often used to delay FDA approval for competitive reasons.); *see* H.R. REP. NO. 104-436, at 5, 9 (1995) (Parties have made anonymous submissions with the sole purpose of delaying agency decisions.); *see FDA Delay in Sucralose Approval Gets "Golden Grinch " Award from Sen. Mathews*, FOOD CHEM. NEWS, Aug. 29, 1994, at 46 (Sen. Harlan Mathews observed that "'any third party could indefinitely delay approval of [a food] additive simply by repeatedly submitting their interpretation of data'"); *see also* Lars Noah & Richard A. Merril, *Starting From Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U.L REV. 329, 330 & 372.

up huge roadblocks and use its connections to cause the FDA to reject the application.[3]

Even many FDA employees are unsettled by their agency's actions.[4] In a recent poll, more than one-third of FDA scientists believed that agency leadership is more concerned with rushing products to market than ensuring consumer safety.[5] To guarantee that products are approved, FDA leaders often pressure scientists to unethically change data or alter their conclusions.[6] Due to the close ties between upper management and the pharmaceutical industry, the FDA is willing to engage in these untoward practices. Unsurprisingly, sixty percent of researchers knew of instances in which industry had inappropriately influenced the FDA's decisions.[7]

The deception is not limited to internal documents. A full twenty percent of FDA scientists "have been asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials."[8] This deceit directly subverts the FDA's mission statement, which lists "helping the public get the

3. *See* Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 58 (allowing industry submissions "brings with it the possibility for strategic manipulation of the regulatory process in pursuit of anticompetitive ends"). We will see this process play out with respect to stevia in Part II.D.

4. Union of Concerned Scientists, Survey: FDA Scientists (2006), http://www.ucsusa.org/scientific_integrity/abuses_of_science/summary-of-the-fda-scientist.html (last visited Apr. 12, 2010) ("The results paint a picture of a troubled agency: hundreds of scientists reported significant interference with the FDA's scientific work, compromising the agency's ability to fulfill its mission of protecting public health and safety.").

5. Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting the Public Health Depends on Independent Science* (2006), *available at* http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf.

6. *Id.* (Eighteen percent of FDA scientists responded, "I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document."); *see also* Gardiner Harris, *F.D.A Scientists Accuse Agency Officials of Misconduct*, N.Y. TIMES, Nov. 18, 2008, at A15. (According to a letter from FDA scientists to Congress, "Top federal health officials engaged in 'serious misconduct' by ignoring concerns of scientists at the Food and Drug Administration and approving for sale unsafe or ineffective medical devices . . . . The letter says that the scientists have documentary evidence that senior agency managers 'corrupted the scientific review of medical devices' by ordering experts to change their opinions and conclusions in violation of the law.").

7. Union of Concerned Scientists, *supra* note 5.

8. *Id.*

accurate, science-based information they need to use medicines and foods to improve their health" as a primary goal.[9]

Unfortunately, nowadays, little things like facts and science are no longer relevant to agency leaders. Their main concern is speeding products through the approval process so pharmaceutical companies can earn more money at the expense of America's health. One FDA scientist from the Center for Drug Evaluation and Research wrote that "[s]cientific discourse is strongly discouraged when it may jeopardize an approval. . . . Whenever safety or efficacy concerns are raised on scientific grounds . . . these concerns are not taken seriously."[10] Quite simply, FDA leaders have failed our nation, and the agency has been captured by the very industries it should be regulating.

On its own website, the FDA plainly states another urgent problem: "The Food and Drug Administration relies on data that sponsors submit to decide whether a drug should be approved."[11] If the FDA hopes to promote public health, it cannot trust corporations to assess the safety and efficacy of their products. The desire to maximize profits all but guarantees that companies will distort their findings.

In fact, entire industries have thrived by "manufacturing uncertainty."[12] Big tobacco is the most prominent,[13] but the examples

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9. FDA, What We Do, http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Apr. 12, 2010).

10. Union of Concerned Scientists, *supra* note 5.

11. FDA, The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last visited Apr. 12, 2010).

12. *See* DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH x (2008) (defining the strategy of "manufacturing uncertainty" as "preventing or postponing the regulation of hazardous products by questioning the science that reveals the hazards in the first place").

13. *See id.* at 9 (The tobacco industry "worked tirelessly for decades to support their preordained conclusions and suppress any findings that suggested otherwise . . . . The industry understood that the public is in no position to distinguish good science from bad. Create doubt, uncertainty, and confusion. Throw mud at the 'antismoking' research under the assumption that some of it is bound to stick. And buy time . . . ."); *see* Deborah E. Barnes & Lisa A. Bero, *Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions*, 279 J. AM. MED. ASS'N. 1566, 1566–69 (1998). The authors determined that "the only factor associated with concluding that passive smoking is not harmful was whether an author was affiliated with the tobacco industry." *Id.* at 1566. They went on to note that the study's "findings suggest that the tobacco industry may be attempting to influence scientific opinion by flooding the scientific literature with large numbers of review articles supporting its position that passive smoking is not harmful to health." *Id.* at 1569.

where corporations have funded scientific studies to manufacture doubt are legion. Some other notable offenders include asbestos,[14] vinyl chloride,[15] and lead.[16] This Article will make the case that the artificial sweetener industry deserves a spot among this illustrious group.

Part I briefly sets the background for artificial sweeteners by describing America's obesity epidemic and sugar addiction. Together, these factors explain why artificial sweeteners have developed into such a profitable industry. Next, Part II explores the controversies surrounding the three most popular artificial sweeteners: saccharin, aspartame, and sucralose. By using artificial sweeteners as a case study, the article shows why the FDA must be reformed.[17] This section will make it clear that the FDA's close ties to pharmaceutical companies and the agency's blind reliance on industry-funded science are threatening consumer safety. Afterwards, Part II further stresses the ill effects of agency capture by describing how industry groups pressured the FDA to ban stevia, a safe, natural sweetener.

After ominously noting that "[t]he Congress and federal agencies are already being dealt with ... by the Tobacco Institute," one tobacco executive suggested that the American people must be made to doubt the scientific evidence regarding the harms of smoking. *See Smoking and Health Proposal*, Brown & Williamson document no. 680561778-1786, 4, *available at* http://legacy.library.ucsf.edu/tid/nvs40f00. The tobacco executive wrote, "Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the minds of the general public. It is also the means of establishing a controversy." *Id.*

14. *See* MICHAELS, *supra* note 12, at 12–18.

15. *See* GERALD MARKOWITZ & DAVID ROSNER, DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION 173–78 (2003). Although the industry knew of vinyl chloride's dangers, it "released only the information that would reassure people as to the essentially benign nature of the finished products." *Id.* at 173. This practice continued for years. "Motivated by money and power rather than health, the industry was largely successful in hiding its information about cancer from the government and in deflecting national attention away from the potential hazards . . . ." *Id.* at 178.

16. *See id.* at 60–64. (After independent studies determined that lead is poisonous, the Lead Industry Association "portray[ed] this growing body of scientific literature as 'prejudice against lead' rather than the documentation of a serious public health concern. The [Lead Industry Association] still sought to cast doubt on virtually every report of lead poisoning, focusing on the reports' methodological problems rather than the underlying reality." To manufacture uncertainty, the lead industry mounted a "thirty-five year advertising campaign to convince people that lead was safe.").

17. Change is unlikely to be initiated by the legislative or executive branch. Even President Clinton instructed the FDA to treat the pharmaceutical companies as "partners, not adversaries." David Willman, *How a New Policy Led to Seven Deadly Drugs*, L.A. TIMES, Dec. 20, 2000, *available at* http://www.latimes.com/news/nationworld/nation/la-122001fda,1,539362.story.

Finally, Part III proposes two potential reforms. Americans must lock the revolving door and take industry out of the approval process. Only then should we trust the FDA with our health.

I. THE OBESITY EPIDEMIC

A. Economic Effects

Calories in – Calories out = Change in bodyweight.

This equation is the key to combating obesity.[18] Start with the number of calories eaten in a day, and subtract the number of calories burned. If the result is positive, you gain weight. If it is negative, you lose weight.

Every 3500 calories adds up to an extra pound.[19] Whether the caloric excess come from apples or chocolate cake, the same amount of weight is gained. This means someone can get fat from eating health foods such as fruits, vegetables, whole grains, and lean meats. Likewise, one could eat nothing but McDonald's Big Macs and manage to lose weight.[20] It all comes down to calories in versus calories out. The key to weight control really is that simple.

Despite this clear formulation, obesity is a growing problem. In 2006, the Centers for Disease Control and Prevention (CDC) conducted a study to determine what proportion of Americans have a weight problem.[21] The CDC derived its data by calculating people's Body Mass Index (BMI).[22] The following table illustrates how BMI relates to the various weight categories.[23]

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18. *See* Frank M. Sacks et al., *Comparison of Weight-Loss Diets with Different Compositions of Fat, Protein, and Carbohydrates* 360 NEW ENG. J. MED. 859, 859 (2009) (concluding that "[r]educed-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize").

19. ROBERTA LARSON DUYFF, AMERICAN DIETETIC ASSOCIATION COMPLETE FOOD AND NUTRITION GUIDE 29 (2002).

20. Obviously, for nutritional reasons, such a diet would be a poor choice.

21. Centers for Disease Control and Prevention, Obesity and Overweight, http://www. cdc.gov/nchs/fastats/overwt.htm (last visited Apr. 12, 2010).

22. Because BMI is derived solely from height and weight, some athletes or bodybuilders may be misclassified as overweight even though they have low body fat percentages. However, because only a small percentage of people fall within these exceptions, the CDC's findings are still useful. For the general population, there is a strong correlation between body fat and BMI. *See* Magnus Dencker et al., *BMI and Objectively Measured Body Fat and Body Fat Distribution in Prepubertal Children*, 27 CLINICAL PHYSIOLOGY AND FUNCTIONAL IMAGING 12, 12–16 (2006) (concluding that "[p]ercentage body fat [was] closely associated with BMI, suggesting that

Height	Weight	BMI	Considered
5'9"	124 lbs or less	Below 18.5	Underweight
5'9"	125 lbs to 168 lbs	18.5 to 24.9	Healthy weight
5'9"	169 lbs to 202 lbs	25.0 to 29.9	Overweight
5'9"	203 lbs or more	30 or higher	Obese

The data show that thirty-four percent of Americans over age twenty are obese and another thirty-three percent are overweight.[24] Eighteen percent of adolescents and more than ten percent of children are overweight.[25] Another eight to nine percent of Americans are underweight,[26] and, incredibly, only one-quarter of Americans are a healthy weight. More adults fall into the obese category than any other classification. Today, obese people outnumber healthy and underweight individuals combined, and the problem is only getting worse. Thomas Frieden, the head of the CDC noted that "[t]he average American is now 23 pounds overweight and collectively we are 4.6 billion pounds overweight."[27] In other words, Americans have eaten sixteen trillion calories too many.[28]

The National Center for Health Statistics found that between 1960 and 2006, the percentage of obese adults has nearly tripled.[29]

BMI serves as a good surrogate marker for obesity in population studies"); *See* Centers for Disease Control and Prevention, About BMI for Adults, http://www.cdc.gov/healthyweight/assessing/bmi/ adult_bmi/index.html ("BMI does not measure body fat directly, but research has shown that BMI correlates to direct measures of body fat . . . .").

23. Centers for Disease Control and Prevention, Overweight and Obesity: Defining Overweight and Obesity, http://www.cdc.gov/obesity/defining.html (last visited Apr. 12, 2010).

24. Centers for Disease Control and Prevention, *supra* note 21.

25. *Id.*

26. Meghan A.T.B. Reese, *Underweight: A Heavy Concern* TODAY'S DIETITIAN Jan. 2006, at 56, *available at* http://www.todaysdietitian.com/newarchives/tdjan2008 pg56. shtml.

27. Thomas Frieden, Director, Centers for Disease Control and Prevention, CDC Weight of the Nation Press Briefing (July 27, 2009), *available at* http://www.cdc.gov/media/transcripts/2009/t090727.htm.

28. Sixteen trillion calories is equivalent to nine billion Burger King Whopper meals with large fries and a large soda. *See* Shereen Jegtvig, *Burger King® Whopper® With Cheese, Large Fries and a Large Soda,* http://nutrition.about.com/od/rateameal/a/ whoppermeal.htm (last visited Apr. 12, 2010).

29. National Center for Health Statistics, Prevalence of Overweight, Obesity, and Extreme Obesity among Adults: United States, Trends 1960-62 through 2005-

During this same period, the proportion of Americans who are "extremely obese" increased more than 600%.[30]

This shift seems to indicate a fundamental change in caloric intake and expenditure.[31] Indeed, over that time, the "calories in" and "calories out" variables in the equation have shifted drastically.[32] Americans now eat more[33] and exercise less.[34] In 1958, the average American consumed less than 1900 calories per day.[35] By 2007, that number had grown to 2,775,[36] more than 500 calories above the USDA's Recommended Energy Allowance of 2,247.[37]

If people needed these extra calories to supply energy for increased physical activity, this trend would not be troubling. We can return to the formula to see why. If the number of calories burned

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2006, http://www.cdc.gov/nchs/data/hestat/overweight/overweight_adult.htm (noting an increase from 13.4% to 35.1%).

30. *Id.* (noting an increase from 0.9% to 6.2%).

31. *See* World Health Organization, Obesity and Overweight, http://www.who.int/dietphysicalactivity/publications/facts/obesity/en (last visited Apr. 12, 2010) ("The key causes [of obesity] are increased consumption of energy-dense foods high in saturated fats and sugars, and reduced physical activity.").

32. For a graph charting the increase in caloric intake from 1970–2000, *see* Judy Putnam, Jane Allshouse, & Linda Scott Kantor, *U.S. Per Capita Food Supply Trends: More Calories, Refined Carbohydrates, and Fats*, 25 FOOD REV. 2, 3, Winter 2002, *available at* http://www.ers.usda.gov/publications/FoodReview/DEC2002/frvol25i3.pdf.

33. Judy Putnam, *U.S. Food Supply Providing More Food and Calories*, 22 FOOD REV. 2, 2, Sep.-Dec. 1999, *available at* http://www.ers.usda.gov/publications/ foodreview/sep1999/frsept99.pdf (noting that "[a]ll three major per capita food supply measurements–food available for consumption, nutrients available for consumption, and the food supply adjusted for spoilage and other losses in the home and marketing system–suggest that Americans in the 1990's are consuming more food and several hundred more calories per person per day than did their counterparts in the late 1950's.").

34. *See* Dana E. King et al., *Adherence to Healthy Lifestyle Habits in US Adults, 1988–2006*, 122 AM. J. MED. 528, 530 (2009) ("The percent of adults aged 40–74 [engaged in] physical activity 12 times a month or more has decreased from 53% to 43%"). Incredibly, in gym class, children are active an average of 3.5 minutes. KELLY D. BROWNELL & KATHERINE BATTLE HORGEN, FOOD FIGHT 78 (2004).

35. Putnam, *supra* note 33, at 2.

36. UNITED STATES DEPARTMENT OF AGRICULTURE, ECONOMIC RESEARCH SERVICE, LOSS-ADJUSTED FOOD AVAILABILITY DATA, *available at* http://www.ers.usda.gov/data/foodconsumption/FoodGuideSpreadsheet.htm#calories.

37. Linda Scott Kantor, Food and Rural Economics Division, Economic Research Service, U.S. Dept. of Ag., Agricultural Economic Report No. 772, A DIETARY ASSESSMENT OF THE U.S. FOOD SUPPLY: COMPARING PER CAPITA FOOD CONSUMPTION WITH FOOD GUIDE PYRAMID SERVING RECOMMENDATIONS (1998), *available at* http://www.ers.usda.gov/publications/aer772/aer772.pdf; *see also* MARION NESTLE, FOOD POLITICS 8 (2002) (noting that "overeating [is] the most probable cause of excessive weight gain").

had increased alongside the number of calories consumed, the equation would have remained in stasis, and obesity would not be a problem. Unfortunately, the exact opposite has occurred. People are now burning fewer calories and are less active than at any other time in our history.[38]

The U.S. Bureau of Labor Statistics found that, on an average day, only sixteen percent of Americans participate in sports or exercise activities.[39] In another study, the CDC determined that fifty-five percent of adults do not meet the minimum level of recommended exercise (thirty minutes of moderate activity five times per week).[40] Although this sounds like a lot of exercise, activities such as vacuuming and gardening meet the CDC's requirements for "moderate activity." Surprisingly, even under this lenient definition, twenty-six percent of Americans fail to get any physical activity.[41]

These statistics should trouble us because poor diet and physical inactivity cause 16.6% of all deaths in America.[42] More specifically, twenty-three percent of the deaths from major chronic diseases–such as stroke, heart disease, and diabetes–are caused by Americans' sedentary lifestyle.[43] Proper nutrition and exercise could save 400,000 American lives every year.[44]

The problems of obesity, however, are not confined to the overweight individuals themselves. Losing excess weight is not just about looking and feeling better; there are also powerful economic reasons to trim the fat. With obesity-related diseases costing the medical system an additional $147 billion annually, obesity is now a greater burden on the health care system than cigarettes or alco-

38. *See* World Health Organization, *supra* note 31 ("[L]arge shifts towards less physically demanding work have been observed worldwide. Moves towards less physical activity are also found in the increasing use of automated transport, technology in the home, and more passive leisure pursuits.").

39. U.S. Bureau of Labor Statistics, *BLS Spotlight on Statistics: Sports and Exercise*, May 2008, *available at* http://www.bls.gov/spotlight/2008/sports/pdf/sports_bls_spotlight. pdf (last visited Apr. 9, 2010).

40. Centers for Disease Control and Prevention, *Prevalence of Physical Activity, Including Lifestyle Activities Among Adults–United States, 2000–2001*, 52 MORBIDITY & MORTALITY WKLY. REP. 764, 764–79, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5232a2.htm (last visited Apr. 9, 2010).

41. *Id.*

42. Ali H. Mokdad et al., *Actual Causes of Death in the United States, 2000*, 291 J. AM. MED. ASS'N. 1238, 1238 (2004).

43. Robert A. Hahn et al., *Excess Deaths from Nine Chronic Diseases in the United States*, 1986, 264 J. AM. MED. ASS'N. 2654, 2656 (1990).

44. *See* Mokdad, *supra* note 42, at 1240.

hol.[45] On average, an obese individual spends forty percent more on health care than a normal-weight person.[46] That amounts to an extra $1500 per year for every overweight person. Approximately half of that cost is born by Medicare and Medicaid.[47] That means you, the taxpayer, are subsidizing other people's bad decisions.

Although the most direct effects of obesity are felt by the health care system, its problems are not limited to that sector. The entire U.S. economy suffers due to decreased productivity. Annually, obesity causes the loss of 39.3 million workdays. It is also responsible for 239 million restricted-activity days, 89.5 million bed days, and 62.7 million physician visits.[48] These direct economic effects check in at $254 billion, nearly twice as high as the medical costs.[49] In comparison, smoking only reduces productivity by seventy-nine billion dollars.[50]

Curing the obesity problem would not only increase economic output, it would also redirect current spending. Overweight drivers burn an additional one billion gallons of gas each year.[51] Airlines would save another billion gallons of gas, and the industry would actually become profitable once again. Clothing costs would be reduced by ten billion dollars, and food expenditures would decline by the billions.[52] Between the direct effects on the economy and health care, obesity costs the nation $487 billion per year.[53] Eliminate all these expenses and each U.S. household would end the year with an extra $4,270 in its checking account.[54]

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45. Roland Sturm, *The Effects of Obesity, Smoking, and Drinking on Medical Problems and Costs* 21 HEALTH AFF. 245, 245 (2002).

46. Frieden, *supra* note 27.

47. Centers for Disease Control and Prevention, Obesity and Overweight: Economic Consequences, http://www.cdc.gov/obesity/causes/economics.html (last visited Apr. 9, 2010).

48. Anne M. Wolf & Graham A. Colditz, *Current Estimates of the Economic Cost of Obesity in the United States*, 6 OBESITY RES. 97 (1998).

49. Ross DeVol & Armen Bedroussian, *An Unhealthy America: The Economic Burden of Chronic Disease–Charting a New Course to Save Lives and Increase Productivity and Economic Growth* ii-iii (2007), *available at* http://www.milkeninstitute.org/pdf/chronic_disease_report.pdf.

50. *Id.* at iii.

51. Shirley Skeel, *What if no One were Fat?*, http://articles.moneycentral.msn.com/Insurance/Advice/WhatIfNoOneWereFat.aspx (last visited Apr. 9, 2010).

52. *Id.*

53. *Id.*

54. *Id.*

Unfortunately, this is just the tip of the iceberg. Once reduced longevity and quality of life are taken into consideration, the true cost is incalculable.[55] Being overweight reduces one's life-expectancy by three years, and being obese reduces one's life-expectancy by 6.5 years.[56] For comparison, smoking has a similar effect on longevity.[57] Not only do overweight people die sooner, but also their quality of life is lower.[58]

If the problems from obesity are so serious and the formula to shed those excess pounds is so simple, why are two-thirds of Americans overweight? An insatiable sweet tooth is a major cause.

B. The Sugar Addiction

On the one hand, sugar[59] is delicious. On the other hand, sugar causes premature aging,[60] diabetes, and heart disease, raises cholesterol and blood pressure,[61] suppresses the immune system,[62] and

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55. *See* David S. Ludwig & Harold A. Pollack, *Obesity and the Economy: From Crisis to Opportunity*, 301 J. AM. MED. ASS'N. 533, 534 (noting that the economic and health costs are "likely to be dwarfed by reasonable economic valuation of reduced longevity and quality of life").

56. Anna Peeters et al., *Obesity in Adulthood and its Consequences for Life Expectancy: A Life-Table Analysis*, 138 ANNALS INTERNAL MED. 24, 28 (2003) (see table 3).

57. *Id.* at 24.

58. *See* Jennifer Klingemann et al., *Relationship between Quality of Life and Weight Loss 1 Year after Gastric Bypass*, 26 DIGESTIVE SURGERY 430, 430 (concluding that a reduction in BMI "dramatically" improves health-related quality of life); *See* Rebecca M. Puhl, *Perceptions of Weight Discrimination: Prevalence and Comparison to Race and Gender Discrimination in America*, 32 INT'L J. OBESITY 992, 998 (finding that "weight/height discrimination occurs in employment settings and daily interpersonal relationships virtually as often as race discrimination, and in some cases even more frequently than age or gender discrimination").

59. Throughout the paper, sugar is used to denote the sugar that has been added to foods, not the sugar that occurs naturally in fruits. This added sugar generally takes the form of sucrose (refined table sugar) and high-fructose corn syrup (a mixture of fructose and glucose).

60. *See* Antoine E. Roux et al., *Pro-Aging Effects of Glucose Signaling through a G Protein-Coupled Glucose Receptor in Fission Yeast*, PLOS GENETICS Mar. 2009 at 1 (noting that "substantial evidence supports the idea that excess glucose acts as a pro-aging and pathogenic factor").

61. Harry G. Preuss et al., *Sugar-Induced Blood Pressure Elevations Over the Lifespan of Three Substrains of Wistar Rats*, 17 J. AM. C. NUTRITION 36, 38 (1998) (finding that "rats ingesting diets high in sucrose . . . eventually showed statistically higher [systolic blood pressure] over their lifespan compared to those consuming the baseline").

62. W. M. Ringsdorf et al., *Neutrophilic Phagocytosis and Resistance to Disease*, 52 DENTAL SURVEY 46, 46–48 (finding that drinking twenty-four ounces of cola depresses the activity of neutrophils, white blood cells that kill bacteria).

contributes to obesity. The choice seems obvious, but for most Americans, the short-term benefit of taste outweighs all of these long-term negative effects.

It is quite obvious that Americans have a sweet tooth. The USDA sets the maximum daily allowance of sugar at ten teaspoons, less than the amount of sugar in a twelve-ounce can of Pepsi.[63] The American Heart Association recommends even less: six teaspoons for women and nine teaspoons for men. The average American far exceeds both upper limits, consuming 22.2 teaspoons each day. In 2008, the USDA determined that, after adjusting for loss during transport, processing, and uneaten food, per capita sugar consumption was more than 85 pounds.[64] Each year, every person is eating 154,221 empty calories from sugar.[65] That's more calories than the average person eats in the first two months of the year.

Where is all this added sugar coming from? Soft drinks are by far the biggest contributor, accounting for nearly thirty-three percent of our sugar intake.[66] The sheer amount of soda that we consume is staggering. On average, Americans drink fifty-two gallons of soft drinks a year, and teenage girls get ten to fifteen percent of their total caloric intake from these sugary beverages.[67]

A large part of the remaining two-thirds of our sugar intake is, of course, derived from the usual suspects: sweetened fruit drinks (ten percent), candy (five percent), cake (five percent), cookies (four percent), and cereal (four percent).[68]

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63. Center for Science in the Public Interest, *America: Drowning in Sugar*, http://www.cspinet.org/new/sugar.html (last visited April 11, 2010).

64. *See* USDA, Sugar and Sweeteners Yearbook: Table 51—Refined cane and beet sugar: estimated number of per capita calories consumed daily, by calendar year, http://www.ers.usda.gov/Briefing/Sugar/data.htm (Per capita consumption is 46.8 pounds); *see* USDA, Sugar and Sweeteners Yearbook: Table 52—High fructose corn syrup: estimated number of per capita calories consumed daily, by calendar year, http://www.ers.usda.gov/Briefing/Sugar/data.htm (Per capita consumption is 37.9 pounds).

65. There are four calories in every gram of sugar.

66. John Casey, The Hidden Ingredient that can Sabotage Your Diet, http://www. medicinenet.com/script/main/art.asp?articlekey=56589 (last visited April 11, 2010); Rachel K. Johnson et al., *Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement from the American Heart Association* 120 CIRCULATION: J. AM. HEART ASS'N. 1011, 1011 (2009) (noting that "[s]oft drinks and other sugar-sweetened beverages are the primary source of added sugars in Americans' diets").

67. James E. Tillotson, *Food Brands: Friend or Foe?* NUTRITION TODAY, Mar.–Apr. 2002, at 78–79.

68. Casey, *supra* note 66.

The rest tends to come from "hidden" sugar. Over the years, manufacturers have become ever more creative, managing to hide sugar in even seemingly healthy foods. Ketchup appears innocuous enough, right? After all, it's made from tomatoes, one of the best antioxidants.[69] Well, ketchup producers have managed to squeeze a full teaspoon of sugar into every tablespoon of ketchup.[70] Think about that. One-third of the ketchup bottle is sugar.

Peanut butter is another food that seems healthy. After all, it is filled with "good" mono- and polyunsaturated fats.[71] Unfortunately, many brands have also been loaded with sugar.[72]

Ironically, low-fat foods that are marketed to health conscious consumers are another favorite hiding place for sugar. When manufacturers take out the fat, the product loses its great taste. To compensate, producers add additional sugar. Although low-fat snack foods tend to have fifty-nine percent less fat per serving than their regular counterparts, the low-fat foods contain only fifteen percent fewer calories.[73]

At first glance, a fifteen percent reduction may still seem like a positive step. However, people tend to eat larger quantities of low-fat foods, more than offsetting any potential caloric savings.

In one study, researchers gave half the subjects a bowl of "low-fat" granola. The remaining subjects were given a bowl of regular granola. Although the granola in both bowls were identical, the subjects who believed the granola were low-fat ate forty-eight percent more.[74] The researchers concluded as follows:

> If participants in [the study] had eaten real low fat granola, and if the low fat granola had the average level of fat and calories for the category, participants would have consumed 35% less fat from the low fat granola

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69. *See* Jeanie Lerche Davis, *The Tasty Tomato: An Antioxidant Power Blast*, http://www.webmd.com/food-recipes/features/tasty-tomato-antioxidant-power-blast (last visited April 11, 2010) ("Tomatoes are loaded with health-protective antioxidants such as lycopene, vitamin C, and vitamin A.").

70. *See*, Gayle A. Alleman, *USDA Nutrition Guidelines*, http://recipes.howstuffworks.com/usda-nutrition-guidelines-ga9.htm (last visited April 11, 2010).

71. *See* Walter C. Willett, *Ask the Doctor: Why is Peanut Butter "Healthy" if it has Saturated Fat?*, HARV. HEART LETTER July 2009, *available at* http://www.health.harvard. edu/newsletters/Harvard_Heart_Letter/2009/July/Ask-the-doctor-Why-is-peanut-butter-healthy-if-it-has-saturated-fat.

72. *See* The Daily Plate, *Peanut Butter*, http://www.thedailyplate.com/nutrition-calories/food/jif/peanut-butter (last visited April 11, 2010) (noting that there are three grams of sugar in every serving of Jif Peanut Butter).

73. Brian Wansink & Pierre Chandon, *Can Low Fat Nutrition Labels Lead to Obesity*, 43 J. MARKETING RES. 605, 609 (2006).

74. *Id.* at 611.

> but would have consumed 33% more total calories. This is a conservative estimate . . . [T]he calorie increase would have probably been even higher because the ingredients used to replace fat tend to make people hungrier.[75]

So, we have a situation where people think they are eating fewer calories but are actually consuming thirty-three percent more. If nothing else, one has to marvel at the brilliant marketing. The food industry has managed to increase revenue by producing "health" foods that are more unhealthy than their normal counterparts.

Although not surprising, it is disconcerting that corporations choose to exploit consumer misbeliefs instead of working to correct them. This action does raise an important question. If companies are willing to take advantage of existing consumer ignorance, are they also willing to actively create misperceptions in order to boost profits? As the rest of this article will show, the answer is a resounding yes. From tobacco to trans-fat to artificial sweeteners, the food industry has been waging a war against science. Through backroom political bargains, corporate America and the U.S. government are trading your long-term health for short-term profits.

Returning to our earlier equation,[76] we find that the average American could lose nearly ten pounds a year just by cutting his sugar consumption by a modest twenty-five percent. Keep in mind that, even with this reduction, Americans would still far exceed the USDA maximum daily allowance.

Such a weight loss would go far in alleviating many of the problems discussed in the previous section. Even if Americans compensate by eating additional calories from other foods, it would still be a beneficial dietary change.

This is true because sugar is full of "empty" calories,[77] meaning that it lacks vitamins, minerals, and fiber. These are the nutrients that our bodies need to function properly. Due, in large part, to excessive sugar consumption, most Americans are not getting sufficient quantities of many essential nutrients.[78] Sugar has the effect of

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75. *Id.* at 614.

76. Calories divided by 3,500 equals change in weight. *See* Part I.A for a detailed explanation.

77. Roger W. Miller, *Empty Calories; Putting on Pounds with Poor Nutrition*, FDA CONSUMER, Nov. 1986, *available at* http://findarticles.com/p/articles/mi_m1370/is_v20/ ai_4531709.

78. *See e.g.*, Adit A. Ginde et al., *Demographic Differences and Trends of Vitamin D Insufficiency in the US Population, 1988-2004*, 169 ARCHIVES INTERNAL MED. 626, 631-

crowding out more nutritious foods. As an example, consider the following: "Over the last 16 years, the percent of adults aged 40–74 ... [who eat] 5 or more fruits and vegetables a day has decreased from 42% to 26%."[79] During the same time, sugar consumption has increased significantly.

Given all the harmful effects of sugar and its close association with obesity, it is not surprising that health-conscious Americans are looking elsewhere to satisfy their sweet cravings.

II. ARTIFICIAL SWEETENERS AND STEVIA

Non-caloric and hundreds of times sweeter than sugar, artificial sweeteners seemed like a godsend, both for America's sweet tooth and its waistline. Unfortunately, these products did not live up to their promises.

First, artificial sweeteners lack the magical weight loss properties many people associate with them. In fact, they may actually cause weight gain.[80] It turns out our bodies have a natural ability to count calories based on the sweetness of foods. Artificial sweeteners disrupt that mechanism by tricking our brains into thinking sweet foods have fewer calories. In turn, people overindulge when they eat sweet products, further aggravating the obesity epidemic discussed in the prior sections.

Setting this indirect problem aside, artificial sweeteners are harmful in their own right. Ironically, in a quest to eat healthier foods, the public has embraced even less healthy alternatives. There are currently five FDA-approved artificial sweeteners: saccharin, aspartame, acesulfame potassium, sucralose, and neotame. This paper will focus on the most popular ones: saccharin, aspartame, and sucralose. The first three sections will document the suspicious circumstances surrounding each additive's approval and examine what independent studies actually concluded about these sweeteners. The fourth section will contrast these products with stevia, a safe, natural, non-caloric sweetener. Stevia's lengthy approval history will show that corporations manipulate the FDA to increase their own profits. In the end, regardless of one's thoughts on the merits of

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32 (finding that only one in four Americans gets an adequate amount of Vitamin D).

79. King, *supra* note 34, at 530.

80. *See* T.L. Davidson & S.E. Swithers, *A Pavlovian Approach to the Problem of Obesity*, 28 INT'L. J. OBESITY & RELATED METABOLIC DISORDERS 933, 934–35 (2004).

these sweeteners, the FDA approval process will be cause for concern.

A. Saccharin

In 1879, two researchers at Johns Hopkins University discovered saccharin, the world's first artificial sweetener.[81] Although the scientists realized saccharin's commercial potential early on, the product was not marketed in the United States until 1901. Due to the chemical's intense sweetness,[82] it soon became popular. The sweetener also stirred up controversy.

In 1907, the USDA launched an investigation to determine whether saccharin was safe. Fearing that the USDA would ban the sweetener, future vice president James Sherman met with President Theodore Roosevelt on behalf of a New York food manufacturing firm. Sherman told the President how the sweetener had saved his company thousands of dollars in production costs. Harvey Wiley, the first commissioner of the FDA,[83] also happened to be at this meeting. He was extremely concerned about the dangers of saccharin consumption and warned President Roosevelt that "[e]veryone who ate that sweet corn was deceived. He thought he was eating sugar, when in point of fact he was eating a coal tar product totally devoid of food value and extremely injurious to health."[84] Roosevelt angrily responded, "Anybody who says saccharin is injurious to health is an idiot."[85]

Nevertheless, to placate Wiley, the President appointed a Referee Board of Consulting Scientific Experts to reexamine saccharin's safety. Since the head of the Board was Ira Remsen, one of the Johns Hopkins researchers who discovered the sweetener, the outcome was predetermined.[86] From the beginning, big business had managed to intervene and prevent the government from seriously reviewing saccharin's health risks.

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81. Victoria Gilman, *Artificial Sweeteners*, 82 SCI. & TECH. 43, 43. (2004).

82. Depending on how saccharin is used, it is between 200 and 700 times sweeter than sugar. *See* SUGAR ASS'N, ARTIFICIAL SWEETENERS, http://www.sugar.org/consumers/sweet_by_nature.asp?id=283 (last visited April 2, 2010).

83. At the time, the agency was known as the Bureau of Chemistry.

84. Suzanne White Junod, *Sugar: A Cautionary Tale*, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SelectionsFromFDLIUpdateSeriesonFDAHistory/ucm091680.htm.

85. *Id.*

86. *Id.*

A few years later, World War I sugar shortages created additional demand for saccharin, and with the health concerns forgotten, the artificial sweetener market expanded for half a century. Then, in 1972, the safety controversy was reignited.

That year, saccharin came directly under attack when two studies linked consumption of the sweetener with cancer in lab animals.[87] Although the Delaney Clause now required the FDA to ban saccharin, commissioner Charles Edwards refused to act. In 1977, yet another study linked saccharin to bladder tumors in rats,[88] and within a few years, the carcinogenicity of saccharin was reaffirmed by additional trials.[89]

Within months, Canada instituted a ban on saccharin that is still in effect today.[90] The FDA, now under the leadership of a new commissioner, also proposed a ban. However, fearing large financial losses,[91] the U.S. sweetener industry immediately mounted a campaign to save saccharin.[92] Industry pressure prevailed, and Congress passed the Saccharin Study and Labeling Act which forbade the FDA from banning the sweetener for 18 months.[93] This short-term prohibition has since been extended numerous times,[94] preventing the FDA from regulating saccharin up until the present day.

Although Congress ultimately preempted any saccharin ban, one must wonder why the FDA failed to act sooner. It was not until

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87. PETER BARTON HUTT & RICHARD A. MERRILL, FOOD & DRUG LAW: CASES AND MATERIALS, 923 (2d ed. 1991).

88. 42 FED. REG. 19996, 19999 (proposed April 15, 1977)

89. *See* R.A. Squire, *Histopatholocial Evaluation of Rat Urinary Bladders from the IRDC Two-Generation Bioassay of Sodium Saccharin*, 23 FOOD & CHEM. TOXIC. 491, 493-496 (1985); J.M. Taylor et al, *Chronic Toxicity and Carcinogenicity to the Urinary Bladder of Sodium Saccharin in the In Utero-Exposed Rat*, 54 TOXIC. & APPLIED PHARMA. 57, 74 (1980) (reaffirming that saccharin causes an increase in bladder neoplasia and hyperplasia in rats).

90. *See* Robert Trumbull, *Canada's Saccharin Ban Leaves a Bitter Taste*, N.Y. TIMES, May 14, 1978, at F3.

91. *See id.* (In Canada, "[f]inancial losses to food and beverage concerns have been heavy. The head of one major Canadian concern involved in the saccharin trade said his company had lost two-thirds of its sales. The production chief of another hard-hit company called the costs converting to different food lines crippling.").

92. *See The Great Saccharin Snafu*, CONSUMER REPORTS, July 1977, at 410, 410-14.

93. Pub. L. No. 95-203, § 1, 3; 91 Stat. 1451, 1452 (1977).

94. *See* Pub. L. No. 96-88, § 509(b), 93 Stat. 695 (1979); Pub. L. No. 96-273, 94 Stat. 536 (1980); Pub. L. No. 97-42, § 2, 95 Stat. 946 (1981); Pub. L. No. 98-22, § 2, 97 Stat. 173 (1983); Pub. L. No. 99-46, 99 Stat. 81 (1985); Pub. L. No. 100-71, § 101, 101 Stat. 431 (1987); Pub. L. No. 102-142, 105 Stat. 910 (1991); Pub. L. No. 104-180, § 602, 110 Stat. 1594 (1996).

five years after studies began showing saccharin's carcinogenic properties that the FDA seriously contemplated doing something. When discussing his failure to regulate the sweetener, Commissioner Charles Edwards explained, "American consumers demand the availability of diet food products. It is irrelevant whether these diet products produce quantifiable health benefits or whether consumers simply like them . . . . [Saccharin] has come to be accepted and expected by the American public, and any law which does not recognize this simply will not work."[95]

At its most basic level, this is appealing. Let the American people determine what additives they want to consume. However, Edwards's position breaks down for several reasons. First, by claiming that he deferred to majority rule, Edwards actually undermined majority rule. Because it is impossible for Americans to evaluate the safety of every potential product, they have assigned this task to the FDA. The public essentially views the FDA as "the mechanism through which the government attempts to compel corporations to act responsibly, and to not damage our health . . . ."[96] By allowing saccharin to remain on the market, the FDA is implicitly stating that the sweetener is not a health risk. This seal of approval allows consumers to discount research that provides evidence of saccharin's dangers. Regardless of the FDA's true motives for not banning the sweetener, the fact that it is on the market is a powerful signal of safety.

Second, and more importantly, if the FDA actually wants to respect consumer preferences, it is doing a terrible job. The agency consistently bans safe, natural substances only to turn around and legalize prescription drugs that are nothing more than patented knock-offs.

One of the most egregious examples involves lovastatin and red yeast rice. When the pharmaceutical industry isolated lovastatin, a cholesterol lowering drug, the market potential seemed enormous. There was just one problem. Red yeast rice, a product that had been in the food supply for more than two thousand years,[97] contained monacolin K, a naturally occurring compound identical to

95. Oversight of Food Safety, 1983: Hearings Before the Senate *Comm. on Labor and Human Resources*, 98th Cong., 1st Sess. 21 (1983) (statement of Charles Edwards).

96. *See* MICHAELS, *supra* note 12, at 232.

97. Özlem Erdo rul & Sebile Azirak, *Review of the Studies on the Red Yeast Rice*, 2 TURKISH ELECTRONIC J. BIOTECH. 37, 38 (2004).

lovastatin.[98] Because red yeast rice could not be patented, supplements derived from it would severely hamper sales of lovastatin.

Big Pharma brought this problem to the FDA, and the agency set about finding a solution. The FDA ultimately determined that because red yeast rice contains a substance identical to a drug, it can be regulated as a drug. Essentially, the FDA allowed pharmaceutical companies to patent a substance in red yeast rice. The agency then turned around and banned red yeast rice for containing that patented compound. It is simply incredible that the FDA can redefine a natural substance as a drug and then subsequently ban any natural products that contain the "drug." This would be no different if a pharmaceutical company had patented vitamin C, and the FDA had then banned oranges because they naturally contain vitamin C.

The FDA has proven time and again that it is willing to ban safe products if it will increase the profits of pharmaceutical companies. Some additional examples include L-tryptophan,[99] pyridoxamine (vitamin B6),[100] ephedra,[101] estriol,[102] and even information regarding the health benefits of cherries.[103] One second the FDA proclaims

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98. Mayo Clinic, Red Yeast Rice (Monascus Purpureus), http://www.mayoclinic.com/health/red-yeast-rice/NS_patient-redyeast (last visited Apr. 9, 2010).

99. The FDA banned L-tryptophan but allowed the substance to be used in prescription drugs. This caused the effective price of tryptophan to increase by 500%. The ban was eventually lifted after more than a decade of vocal opposition from consumers and organizations such as the Mayo Clinic. *See* Dean Wolfe Manders, *The FDA Ban of L-Tryptophan: Politics, Profits and Prozac*, 26 SOC. POL'Y. 55, 55–58 (1995).

100. *See* American Association for Health Freedom, When is a Vitamin Not a Vitamin? When the FDA Says So!, http://aahf.nonprofitsoapbox.com/index.php?option= com_content&task=view&id=677&Itemid (last visited Feb. 26, 2010).

101. *See* Mike Adams, *FDA Declares Form of Vitamin B6 a Drug, Effectively Banning Pyridoxamine from Dietary Supplements*, http://www.naturalnews.com/025606.html (last visited Feb. 26, 2010) ("The same thing happened with ephedra, a Traditional Chinese Medicine herb known as *ma huang*. The FDA banned the herb, saying it was 'dangerous at any dose,' but pharmaceuticals containing the very same molecules (ephedrine) are still being sold over-the-counter as cold medicines, meaning they're available to any child without a prescription.").

102. *See* American Association for Health Freedom, *Natural Substance Knock Offs in the FDA Pipeline Could be Dangerous*, Sep. 6, 2008, http://foodconsumer.org/7777/8888/C_onsumer_A_ffair_26/090606512008_Natural_Substance_Knock_Offs_in_the_FDA_Pipeline_Could_be_Dangerous.shtml.

103. *See* American Association for Health Freedom, *Big Pharma and the FDA: Suppress the Science, Ban the Natural Substances, Sell the Drugs*, http://www. organiconsumers.org/articles/article_18219.cfm (last visited Feb. 26, 2010) ("When the 2005 ban was instituted, the FDA sent warning letters to twenty-nine companies that

that a natural substance is dangerous, despite independent scientific consensus to the contrary. The very next moment, it determines that a prescription drug derived from that same substance is perfectly safe.[104] The Article will further explore the FDA's double standard with respect to the natural sweetener stevia in Part II.D.

The agency's past actions have led to a worrisome process: base approval decisions on consumer preferences when doing so enriches big business, and base approval decisions on food safety when doing so enriches big business. This shadowy practice does make one thing very clear. The FDA is broken.[105] The following sections will make it even more apparent that the agency must be reformed.

B. Aspartame

Consumed by over two hundred million people and used in more than six thousand products, aspartame is the king of artificial sweeteners.[106] In the U.S., it is marketed under the brand names NutraSweet and Equal. Aspartame is found in everything from diet sodas and sugar-free desserts to children's vitamins[107] and vegetable juice.[108] At one point, it accounted for sixty-two percent of the world artificial sweetener market.[109] Americans alone ingest more than 8,000 tons of aspartame each year.[110] That statistic is even more in-

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market cherry products. In these letters, they ordered the companies to stop publicizing scientific data about cherries. According to the FDA, when cherry companies disseminate this peer-reviewed scientific information, the cherries become 'unapproved new drugs' and are subject to seizure. The FDA warned that if those involved in 'cherry trafficking' continue to inform consumers about these scientific studies, criminal prosecutions would ensue.").

104. *See* Adams, *supra* note 101 (noting that "another classic oppression tactic of the FDA [is to] [b]an the herb, but promote the drug using the same chemicals").

105. *See, e.g.*, American Association for Health Freedom, *supra* note 102 (arguing that, if you pay off the FDA, "the Agency will try to reward you with monopoly control of the market").

106. Aspartame Information Center, Products, http://www.aspartame.org/aspartame_products.html (last visited Apr. 9, 2010).

107. *See, e.g.*, Bayer, Flintstones FAQs, http://flintstonesvitamins.com/faqs (last visited Apr. 9, 2010) (stating that "the Flintstones Complete formula and Plus Calcium formula contain aspartame").

108. For a partial list of products containing aspartame, see Aspartame Information Center, *supra* note 106.

109. James Fry, *The World Market for Intense Sweeteners*, 85 WORLD REV. NUTRITION & DIETETICS 201, 204 (1999).

110. United States National Library of Medicine, Hazardous Substances Data Bank: Aspartame, http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB (search for "aspartame") (last visited Apr. 9, 2010).

credible when one considers that aspartame is 200 times sweeter than table sugar.[111] This sweetener has become so pervasive that it is almost impossible to find certain consumer products without it.[112]

In addition to being the most prominent artificial sweetener in the world, aspartame also has the distinction of receiving more complaints than any other substance in FDA history.[113] By 1992, Americans had filed more than ten thousand aspartame-related complaints, and approximately eighty percent of all non-drug complaints to the FDA involved the sweetener.[114] People complained that aspartame caused, among other side effects, headaches, rashes, dizziness, menstrual problems, and seizures.[115] Unfortunately, because the FDA stopped tracking aspartame complaints in 1992, the current number of aspartame-related problems is unavailable.[116] Nevertheless, the danger is still present. The following sections will examine the evidence regarding aspartame's safety and the unsettling circumstances surrounding its approval.

1. The Evidence

In the course of writing *Aspartame Disease: An Ignored Epidemic*, the author clinically observed 1200 patients who had suffered aspartame reactions. He found that common side effects include vision problems, tinnitus, headaches, memory loss, depression, heart palpitations, diarrhea, itching, and severe joint pain.[117] Additional studies have reinforced these observations, strengthening the link between aspartame and depression,[118] headaches,[119] and seizures.[120] Other case

111. Sugar Association, *supra* note 82.

112. Nearly every brand of chewing gum has aspartame. Even gum that contains sugar is now supplemented with the artificial sweetener. *See e.g.*, Wrigley, Doublemint, http://www.wrigley.com/global/brands/ doublemint.aspx (last visited Apr. 9, 2010) (indicating that regular Doublemint gum now includes sugar, aspartame, and acesulfame K).

113. Aspartame earned this honor in just three short years. *See* Janet Starr Hull, *How Many Aspartame Complaints are Registered with the FDA?*, Oct. 7, 2005, http://www.janethull.com/askdrhull/article.php?id=044.

114. *Id.*

115. 131 CONG. REC. 9981, 10807 (1985).

116. *See* Janet Starr Hull, *Is it True that the Majority of FDA Complaints are for Aspartame?*, Oct. 7, 2005, http://www.janethull.com/askdrhull/article.php?id=043 (The FDA "began putting the complaints into generic categories not related to aspartame, such as death. If death by seizure was reported as a reaction to aspartame, the death was recorded as seizure only and not as an 'aspartame' seizure.").

117. *See* ROBERTS, *supra* note 1, at 68-71.

118. *See* Ralph G. Walton et al., *Adverse Reactions to Aspartame: Double-blind Challenge in Patients from a Vulnerable Population*, 34 BIOLOGICAL PSYCHIATRY 13, 13

studies have also connected aspartame to "angry outbursts",[121] skin lesions,[122] and panic attacks.[123] Aspartame has even been linked to cancer.[124] The FDA complaints present a similarly stark picture.[125]

Given all of these dangerous side effects, how could the FDA have ever approved this artificial sweetener? Well, it turns out that there is also evidence supporting aspartame's safety. Funding for the trials providing this "evidence," however, came from the NutraSweet industry. A survey of aspartame research found that "[o]f the 166 studies felt to have relevance for questions of human safety, 74 had NutraSweet industry related funding and 92 were independently funded. One hundred percent of the industry funded research attested to aspartame's safety, whereas 92 percent of the independently funded research identified a problem."[126]

These numbers actually understate the unanimity of independent scientific opinion. Of the seven non-industry funded studies that were favorable to aspartame, one was a literature review that focused on industry research, and six were conducted by the FDA.[127] Due to the FDA's pro-business bias and controversial ties to G.D.

(1993) (concluding "that individuals with mood disorders are particularly sensitive to this artificial sweetener and its use in this population should be discouraged").

119. *See e.g.*, Stephen K. Van Den Eeden et al., *Aspartame Ingestion and Headaches: A Randomized Crossover Trial*, 44 NEUROLOGY 1787, 1787 (1994) ("Subjects reported headaches on 33% of the days during aspartame treatment . . . ." The paper concluded "that some people are particularly susceptible to headaches caused by aspartame and may want to limit their consumption."); *see e.g.*, Rebecca B. Lipton et al., *Aspartame as a Dietary Trigger of Headache*, 29 HEADACHE 90, 90 ("[A]spartame may be an important dietary trigger of headache in some people.").

120. *See* T.J. Maher & R.J. Wurtman, *Possible Neurologic Effects of Aspartame, a Widely Used Food Additive*, 75 ENVTL. HEALTH PERSP. 53, 56 (1987).

121. *See* 131 CONG. REC. 10,805–6 (1985).

122. *See* Nelson Lee Novick, *Aspartame-Induced Granulomatous Panniculitis*, 102 ANNALS INTERNAL MED. 206, 206–7 (1985).

123. *See* J.M. Ferguson, *Panic Attacks and Excessive Aspartame Ingestion*, 328 LANCET 631, 631 (1986).

124. *See* John Olney et al., *Increasing Brain Tumor Rates: Is There a Link to Aspartame?*, 55 J. NEUROPATHOLOGY & EXPERIMENTAL NEUROLOGY 1115, 1115–23 (1996) (concluding that "there is need for reassessing the carcinogenic potential of aspartame"); *see generally* Morando Soffritti et al., *First Experimental Demonstration of the Multipotential Carcinogenic Effects of Aspartame Administered in the Feed to Sprague-Dawley Rats*, 114 ENVTL. HEALTH PERSP. 379, 379–85 (2006).

125. *See* ROBERTS, *supra* note 1, at 72.

126. Ralph G. Walton, Survey of Aspartame Studies: Correlation of Outcome and Funding Sources (1998) (unpublished manuscript, *available at* http://www.dorway.com/peerrev.html).

127. *Id.*

Searle, the maker of aspartame, the independence of these six studies is questionable.[128]

Moreover, thirty-three of the industry funded studies were, with minor changes, published in different journals from two to six times each.[129] Repeatedly publishing the same study in multiple journals is a deceptive and unethical practice commonly employed by pharmaceutical companies.[130] It seems that Searle was more interested in swamping the media with pro-aspartame studies than in actually ascertaining the safety of a product that could harm millions of people.[131]

Aspartame producers routinely state that the sweetener is the most tested food additive ever approved by the FDA. However, this wonderful marketing line hides the fact that a single valid study is more useful than any number of flawed studies. Because Searle could not boast of the quality of its studies, the company relied on sheer quantity. The experiments were so poorly run that Alexander Schmidt, the FDA commissioner at the time Searle submitted its research, called the studies "incredibly sloppy science," adding that "[w]hat was discovered was reprehensible."[132]

Two of the most extensive trials on aspartame were run by a group of Italian researchers.[133] Unlike the Searle safety tests, their studies were both independently funded and published in peer-reviewed journals, the gold standard in science. The scientists were motivated to perform their first "mega-experiment" because Searle's studies "did not comply with today's basic requirements for testing the carcinogenic potential of a physical or chemical agent."[134] In particular, the scientists noted that Searle's experiments were termi-

128. *See infra* Part II.B.2.

129. Walton, *supra* note 126 (indicating that "[v]irtually all journals require that an affidavit be signed by all authors to the effect that neither the manuscript nor the data it contains have been previously published or concurrently submitted elsewhere for publication. Violation of this policy may have a detrimental impact on scientific progress and ethics.").

130. *See* MICHAELS, *supra* note 12, at 149.

131. Many industries have employed a similar strategy. *See supra* notes 13–16 and accompanying text.

132. 131 CONG. REC. 10,808 (1985).

133. *See* Soffritti *supra* note 124; Morando Soffritti et al., *Life-Span Exposure to Low Doses of Aspartame Beginning during Prenatal Life Increases Cancer Effects in Rats*, 115 ENVTL. HEALTH PERSP. 1293, 1293 (2007).

134. Soffritti, *supra* note 124 at 380.

nated prematurely and failed to include a large enough population sample.[135]

A major purpose of this study was to determine a safe acceptable daily intake (ADI) for aspartame. On the basis of Searle's trials, the FDA set the ADI at 50 mg/kg of bodyweight.[136] In more concrete terms, a 150-pound adult would need to drink twenty cans of diet soda to reach this limit.[137] The makers of aspartame went even further, claiming that not even this high amount would be dangerous because the ADI has a "built-in safety factor."[138]

Since most people do not consume that much aspartame, Soffritti and his group of researchers sought to determine if aspartame is a carcinogen when ingested in smaller quantities. Their study showed that aspartame's "carcinogenic effects are evident even at a daily dose of 20 mg/kg of bodyweight."[139]

This is the equivalent of eight cans of diet soda, a limit many Americans exceed.[140] Because aspartame is found in over 6,000 products, it is easy to see how a person can quickly surpass this level. Nonetheless, aspartame proponents are likely to claim that this is a relatively high limit, so it is still safe to ingest a lesser amount of aspartame on a daily basis.

However, just because most people drink less does not mean they are safe from the harmful effects. Recall that the FDA set the ADI at fifty mg/kg of bodyweight. Soffritti's team of researchers showed that aspartame is carcinogenic at a mere forty percent of the FDA's supposedly safe level. Future research at lower quantities is necessary, but the outcome for aspartame looks bleak.

To see why, it is perhaps easiest to draw an analogue to smoking. Adhering to the previous ratios, the FDA has, in effect, claimed that smoking five packs of cigarettes a day is safe. Soffritti's study showed that not even two packs a day would be safe. Although we

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135. *Id.* FDA statistician Robert J. Condon expressed similar concerns, finding problems in the conduct and power of the studies. 131 CONG. REC. 10,807 (1985). Satya D. Dubey, a statististician at the FDA's Center for Drugs and Biologics also noted "certain statistical difficulties" with Searle's studies. *Id.*

136. The NutraSweet Company, How much aspartame do people actually consume?, http://www.nutrasweet.com/articles/article.asp?Id=46 (last visited Apr. 2, 2010).

137. *Id.*

138. *Id.*

139. Soffritti *supra* note 124, at 384.

140. *Good Morning America* (ABC television broadcast May 19, 2007), *available at* http://abcnews.go.com/GMA/weekend/story?Id=3191903&page=1.

would certainly want to explore whether smoking fewer cigarettes would cause cancer, even pack-a-day smokers should be worried.

The equivalent holds true for aspartame. The FDA has set a high ADI of twenty cans of diet soda for the average adult. Scientists undercut this number by showing that consuming a more plausible eight cans of diet soda increases the likelihood of cancer. At this point, even people who only drink a few cans of diet soda a week may want to consider whether it is worth the health risk.

The same group of researchers conducted an additional experiment that confirmed the first study and further determined that, when pregnant rats eat aspartame, there is an increased incidence of cancer among their offspring.[141]

Unhappy with these results, the aspartame industry went on the offensive by funding a literature review that attacked the Soffritti studies.[142] This particular piece was sponsored by Ajinomoto, a Japanese supplier of aspartame. Therefore, it is not surprising that the authors of the review accepted industry-research as gospel and discounted any independently-funded research that showed evidence of aspartame's dangers. Interestingly, after this review concluded that the sweetener's "safety is clearly documented," Ajinomoto rebranded aspartame as AminoSweet. The company did this to hide aspartame's history of causing health problems and to trick the public into thinking it is a natural product.[143]

Given all of this evidence, one cannot help but wonder how aspartame has remained on the market for nearly thirty years. The FDA's close relationship with G.D. Searle will resolve this mystery. Unfortunately, the FDA—the very agency established to protect Americans from unsafe food and drugs—placed corporate earnings above our health.

2. FDA Approval

G.D. Searle, the creator of aspartame, has an extensive history of manipulating reports to hide the dangers of its drugs. Between

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141. *See* Life-Span Exposure, *supra* note 133, at 1297 (demonstrating that "when life-span exposure to APM [aspartame] begins during fetal life, its carcinogenic effects are increased").

142. B.A. Magnuson et al., *Aspartame: A Safety Evaluation Based on Current Use Levels, Regulations, and Toxicological and Epidemiological Studies*, 37 CRITICAL REV. TOXICOLOGY 629, 669 (2007).

143. *See* Ethan Huff, Aspartame Has Been Renamed and is Now Being Marketed as a Natural Sweetener, http://www.naturalnews.com/028151_aspartame_sweeteners.html (last visited Apr. 2, 2010).

1975 and 1977 alone, the FDA investigated Searle for fraud involving the safety testing of Aldactone, Flagyl, Norpace, and aspartame.[144] The FDA reported its findings to the Subcommittee on Health of the Senate Judiciary Committee, and what they found was startling. In some of the Aldactone studies, gross legions requiring histopathological examinations were never examined, malignant tumors were removed and never reported, and a full thirty percent of the animal tissues earmarked for examination were never examined.[145] FDA commissioner Alexander Schmidt noted one study was so bad that even "after three separate reviews by Searle personnel of the same data . . . we are continuing to discover errors that complicate review of this study."[146]

Searle used even more dubious practices while preparing reports for its other drugs. In the clinical trials for Flagyl, Searle often had two pathologists examine the animals. When the pathologists' opinions differed, Searle used the reports that cast Flagyl in the more favorable light,[147] and any data that questioned Flagyl's safety was conveniently withheld from the FDA. Searle went even further in its quest to approve aspartame. When pathologists submitted unfavorable reports, Searle simply changed the findings.[148]

In a study of the drug Norpace, the FDA found "inadequate ante-mortem observations: e.g. animals reported in good condition were actually dead . . . ."[149] Searle's data are so contradictory that individual rats die and come back to life as many as four times. When manipulating data wasn't enough, Searle forced its scientists to lie. Despite voicing his objections, John W. Sargatz, Searle's principal pathologist, was ordered to write "reassuring comments on post-mortems of rats . . . ."

This pattern of serious errors led the FDA to question the validity of all of Searle's studies. The agency noted that "the *cumulative* findings of problems within and across the studies we investigated

144. JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY 75–78 (1984).

145. *Id.* at 76.

146. *Id.*

147. *Id.* In a 1976 report to the Subcommittee on Health of the Senate Judiciary Committee, FDA Commissioner Alexander Schmidt criticized Searle for this practice.

148. *Id.* at 77 (Commissioner Schmidt noted that FDA "investigators found that a pathologist's summary was edited in such a manner as to alter, generally in a favorable direction, some of the pathologist's findings.").

149. *Id.* (internal quotations omitted).

reveal a pattern of conduct which compromises the scientific integrity of the studies."[150]

Due to Searle's actions regarding Aldactone, Flagyl and Norpace, the FDA General-Counsel's office wanted the government to launch a criminal investigation. However, the Justice Department decided that a criminal prosecution would be useless because senior executives would pass the blame to a handful of junior managers.

Searle handled the aspartame approval process in a similarly deceptive manner. In 1980, the FDA had two separate panels evaluate aspartame. Both panels recommended not approving the sweetener due to concerns about brain tumors.[151] The FDA task forces determined that the Searle experiments were seriously flawed.[152] Raw data were missing, and the information that was available contained numerous errors and discrepancies. The Searle's researchers had disposed of dead rats without checking to see if aspartame killed them and had operated on others to remove evidence of tumors.[153] The scientists even secretly administered antibiotics.[154] Searle's scientists also failed to properly mix aspartame with the lab animals' food. This allowed the rats to eat around the chemical. It's pretty hard to find aspartame-related side effects when the rats aren't even ingesting the aspartame.

The tactics uncovered in the FDA reports show that Searle misrepresented the carcinogenic effects of aspartame and hid incriminating data from the agency.[155] Adrian Gross, a lead researcher on the FDA task force, noted the following: "At the heart of FDA's regulatory process is its ability to rely upon the basic safety data submitted by sponsors of regulated products. Our investigation clearly demonstrates that, in the G. D. Searle Co., we have no basis for such reliance now."[156] Gross went on to state that, ironically,

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150. *Id.* (internal quotations omitted).

151. *See 60 Minutes* (CBS television broadcast Dec. 29, 1996), *available at* http://video.google.com/videoplay?docid=5805190307148690830#.

152. *See* FDA, The "Bressler Report", *available at* http://www.dorway.com/bressler.txt.

153. *See 60 Minutes, supra* note 151.

154. *Id.*

155. *Id.* (The FDA investigation revealed "a pattern of conduct which compromises the scientific integrity of the studies." Former Senator Howard Metzenbaum, an active opponent of aspartame, said that "according to the FDA themselves, Searle, in making their presentation to the FDA, had willfully misrepresented the facts and had withheld some of the facts that they knew would possibly jeopardize the approval of the product.").

156. Morton Mintz, *Metzenbaum: NutraSweet Inquiry Needed*, WASH. POST, Feb. 7, 1986, at B9.

Searle's own studies "established beyond a reasonable doubt that aspartame is capable of inducing brain tumors in experimental animals."[157]

FDA officials were so upset by Searle's deception that they sent the file to the U.S. Attorney's office and urged them to present the information to a grand jury. Unfortunately, it was never presented. Samuel Skinner, the head of the grand jury probe, withdrew from the case to accept a position at Searle's Chicago law firm Sidley & Austin. During this delay, the statute of limitations ran out.[158]

Skinner was not the only government official tainted by Searle. After leaving the FDA, former Acting Commissioner Michael Friedman was hired as vice president of G.D. Searle. Unsurprisingly, Friedman defended aspartame by arguing that despite the numerous problems, "the scientists looking at that information decided that the basic strength of the conclusions remains intact."[159] Apparently, Friedman failed to read any of the FDA task force's reports that directly contradict this statement.

The most striking corruption, however, involves FDA Commissioner Arthur Hayes, Jr. and Donald Rumsfeld. Between 1977 and 1985, Donald Rumsfeld served as CEO, President, and eventually Chairman of Searle. On January 21, 1981, a mere day after President Reagan's inauguration, Searle resubmitted its aspartame application to the FDA. Hayes quickly appointed a five-member committee to determine whether aspartame should be approved. When it became apparent that the committee would reject the application by a vote of three to two, Hayes installed a sixth member. This tied the vote and allowed Hayes, as FDA Commissioner, to break the deadlock and approve aspartame. Shortly after this incident, Hayes left the FDA to take a job at Bursen-Marsteller, Searle's public relations firm.[160] Even if one fervently believes that aspartame is safe, this underhanded process by which it was approved should be unsettling.

C. Sucralose

If aspartame is the king of artificial sweeteners, sucralose is the upstart prince making a grab for the crown. Since receiving FDA approval in 1999, sucralose has become the most popular artificial sweetener in the United States and aspartame's main rival in the

157. *Id.*
158. *60 Minutes*, *supra* note 151.
159. *Id.*
160. *Id.*

global market. Sucralose is marketed by McNeil Nutritionals[161] under the brand name Splenda. It is currently used in more than 4,000 products and is 600 times sweeter than sugar.[162] Sucralose's main advantage over aspartame is that it remains stable at high temperatures.[163] This property allows the sweetener to be used in baked goods. Because sucralose can be added to a much wider variety of products, people will have more opportunities to consume it. Therefore, it is even more important to ensure that the sweetener is safe.

Sucralose's problems start with its name. The similarity to sucrose is not a coincidence. McNeil wants the public to think that sucralose is a natural product.[164] Even before approval, consumer advocacy groups alerted the FDA that the name sucralose would create confusion. They suggested that the product be labeled in a manner that would accurately describe its chemical structure.[165] The FDA rejected this idea because other artificial sweeteners had not been named according to this convention.[166] The FDA made the absurd argument that because people had not confused aspartame with sucrose, they would not confuse sucralose with sucrose.

McNeil won this round, but in its quest to fool the public, the company thought that similar names would not be enough. It also developed slogans that would force consumers to mentally align sugar with sucralose. One example is "Think sugar, say Splenda."[167] Another successful approach was to substitute "Splenda" for "sugar" in childhood fairy tales. This led to such memorable advertisements

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161. McNeil Nutritionals is a subsidiary of Johnson & Johnson. Linkedin, McNeil Nutritionals, http://www.linkedin.com/companies/mcneil-nutritionels (last visited Apr. 6, 2010).

162. Tate & Lyle, About SPLENDA® Sucralose, http://www.tateandlyle.com/TateAndLyle/products_applications/_products/sucralose/default.htm (last visited Apr. 6, 2010).

163. *Id.* ("SPLENDA® Sucralose retains its sweetness through all commonly used food and beverage manufacturing processes and also throughout the shelf life of finished products.").

164. McNeil Nutritionals' deceptive marketing has tricked forty-seven percent of Splenda users into thinking that it is a natural product. Center for Science in the Public Interest, "Splenda Should Stop Confusing Consumers, Says CSPI: Statement of CSPI Executive Director Michael F. Jacobson," Feb. 14, 2005 http://www.cspinet.org/new/200502141.html (last visited Apr. 6, 2010).

165. Sucralose's chemical name is trichlorogalactose.

166. FDA Final Rule on Sucralose, §102.5(a), http://vm.cfsan.fda.gov/~lrd/fr980403.html.

167. Pallavi Gogoi, *How Far from Sugar Is Splenda?*, Feb, 2, 2005, *available at* http://www.businessweek.com/technology/content/feb2005/tc2005022_7832_tc024. htm.

as "The Dance of the Splenda Plum Fairy," "Splenda and Spice and Everything Nice," and "Roses are Red, Violets are Blue, Splenda is Sweet and So Are You."[168]

Rival Merisant, the maker of aspartame-based Equal, felt that these marketing techniques had gone too far. In 2006, the company sued McNeil Nutritional for unfair profits and lost sales due to these misleading advertisements.[169] After it became clear that the jury would find against McNeil, the two companies settled.

A major focus of the trial was the main promotional slogan for Splenda: "Made from sugar, so it tastes like sugar."[170] Apparently, the marketing team that thought up this line was unfamiliar with even the most basic principles of chemistry. Two products with similar constituent elements are often vastly different, both in terms of safety and function.[171]

By McNeil Nutritionals' standard, we could create a similar slogan for table salt: "Made from chlorine, so it tastes like chlorine." No doubt this seems laughable. As anyone who has swallowed pool water can confirm, fast food chains are unlikely to start putting chlorine packets next to the salt shaker. Nevertheless, McNeil Nutritionals has successfully promoted sucralose with a slogan that uses identical reasoning.

In its elemental form (Cl_2), chlorine is a powerful disinfectant and bleaching agent. However, when the chlorine atom combines with sodium (Na), we get common table salt (NaCl). One was used

168. For a discussion of McNeil Nutritionals' distinct marketing campaign, see Elizabeth Esfahani, Finding the Sweet Spot, Nov. 1, 2005, http://money.cnn.com/magazines/business2/business2_archive/2005/11/01/8362835/index.htm ("[T]he bottom line is, Splenda is not sugar. It is a completely artificial chemical compound.").

169. *See* Amy S. Clark, Equal and Splenda Settle Lawsuit, May 11, 2007 http://www.cbsnews.com/stories/2007/05/11/business/main2793207.shtml (last visited Apr. 6, 2010) ("Merisant was seeking more than $200 million from McNeil – at least $183 million for unfair profits since 2003 and compensation for at least $25 million in lost sales."); For additional details of the lawsuit, see Associated Press, Splenda Settles Lawsuit Over 'Sugar' Claim, May 11, 2007, http://www.msnbc.msn.com/id/18618557 (last visited Apr. 6, 2010).

170. Clark, *supra* note 169.

171. As early as the 1820s, scientists had discovered this property of chemical compounds. *See* JOHN THEODORE MERZ, A HISTORY OF EUROPEAN THOUGHT IN THE NINETEENTH CENTURY 406 (1904) ("Wöhler in 1823, Liebig in 1824, and Faraday in 1825 found that entirely different qualities indicating a different constitution, could belong to bodies that have the same elements in the same numerical proportions.").

as a weapon during World War I,[172] and the other is a common food ingredient.

Another familiar example is carbon monoxide (CO) and carbon dioxide (CO_2). If McNeil Nutritionals were charged with making up a slogan for this gas, it might go something like the following: "Carbon Monoxide! Made with the same elements as carbon dioxide, so it's just as safe as carbon dioxide." Again, this is obviously false, but it operates under the same mistaken assumption as the sucralose slogan, namely that chemicals with similar constituent elements have similar qualities.

Sucrose ($C_6H_{12}O_6$) and sucralose ($C_{12}H_{19}Cl_3O_8$) are even less alike than the preceding examples. McNeil Nutritionals makes sucralose by chlorinating sugar. This process involves replacing three of the hydroxyl groups (OH) with chlorine atoms and results in a major change to the molecular structure. Ethanol provides a clear example of how replacing a hydroxyl group creates an entirely unrelated chemical. When ethanol (C_2H_6O) is chlorinated, it becomes chloroethane (C_2H_5Cl). The substance starts as the alcohol found in drinks and ends up as an effective refrigerant and aerosol spray propellant.

When sugar undergoes this chlorination process to become sucralose, it is converted into a chlorocarbon. McNeil Nutritionals tries to brush this matter aside by pointing out that we eat chlorine every day in the form of table salt. By making this argument, McNeil conveniently ignores a fundamental difference in the chemical bonds. The defining feature of chlorocarbons such as sucralose is a covalently bonded chlorine atom. In table salt, however, sodium and chlorine form an ionic bond to become sodium chloride.[173] The difference between a covalent and ionic bond is night and day.[174]

As a class, chlorocarbons consist of insecticides, pesticides, bleaches, chemical weapons, and sucralose.[175] Because McNeil did

172. *See* New York State Department of Health, The Facts about Chlorine, Aug. 5, 2004, http://www.health.state.ny.us/environmental/emergency/chemical_terrorism/chlorine_tech. htm (last visited Apr. 6, 2010).

173. For further discussion of the difference between chlorine and chloride, see Roald Hoffman, *Legally Sweet*, Vol. 95, 310 (2007), *available at* http://www.americanscientist.org/issues/id.3749,y.0,no.,content.true,page.1,css.print/issue.aspx (last visited Feb. 26, 2010).

174. "If the logic of [McNeil's] argument were correct, we could all be guzzling drain cleaner without consequence because, after all, lye, also known as sodium hydroxide, is merely sodium, hydrogen, and oxygen-all very common components of food." *Sucralose Q&A Setting the Record Straight Part 2*, 1 INTEGRATED SUPPLEMENTS NEWSLETTER, July 2007, at 2, *available at* http://www.integratedsupplements.com/articles/ Newsletter200704.pdf.

175. For a table of chlorocarbons, see MERCOLA, *supra* note 1, at 81-83.

not want its artificial sweetener to be associated with these toxic substances, it created a completely new chemical category: chlorocarbohydrates. Conveniently for McNeil, sucralose is the only chloro-carbohydrate in the world.

Since McNeil Nutritionals can magically create a new chemical category, perhaps it has also miraculously developed a safe chlorocarbon. Let's see what science has to say. McNeil boasts that "[s]ucralose has been extensively tested in more than 100 studies during a 20-year period and found to be a safe and remarkably inert ingredient."[176] This is an incredibly crafty sentence. Anyone who reads it would reasonably assume that those studies were long-term and focused on human safety. Both of these assumptions, however, would be wrong. Only three studies lasted a year or more, and none of those involved humans. On top of this, the vast majority of trials went unpublished. If these unpublished studies had safe results, why would McNeil withhold them from the public? Equally disturbing, more of the published studies examined whether sucralose causes tooth decay rather than if the product is safe to consume.[177] You can sleep soundly at night knowing that McNeil thoroughly investigated any potential dental problems. Unfortunately, whether sucralose has a toxic effect on the rest of your body was not a concern.

The current state of safety literature is reminiscent of aspartame twenty years ago. No long-term studies have been done on humans,[178] the manufacturer's own tests found evidence of toxicity in rats,[179] and consumers have reported many adverse reactions.[180] The Sucralose Toxicity Information Center has received complaints linking the following ailments to sucralose: "skin rashes/flushing, panic-like agitation, dizziness and numbness, diarrhea, swelling,

176. All About Sucralose, Sucralose Facts, http://www.sucralose.org/facts/brochure.asp (last visited Apr. 10, 2010).

177. Oddly, all of the safety studies involving animals were published in a single issue of one journal.

178. *See* MERCOLA, *supra* note 1, at 89 (noting that the longest safety study involving humans was just thirteen weeks).

179. Marcelle Pick, Sugar substitutes and the potential danger of Splenda, Nov. 14, 2005, http://www.womentowomen.com/healthyweight/splenda.aspx (last visited Apr. 10, 2010) (noting that pre-approval studies showed that sucralose "caused shrunken thymus glands, enlarged livers, and kidney disorders in rodents").

180. *See* Food and Diet, Splenda, http://www.foodanddiet.com/NewFiles/splenda-story-list.html (last visited Apr. 8, 2010) (listing consumer complaints that include headaches, depression, anxiety, diarrhea, vomiting, extreme fatigue, drug-like feelings of disorientation and confusion, and more).

muscle aches, headaches, intestinal cramping, bladder issues, and stomach pain."[181]

McNeil Nutritionals states that sucralose "passes rapidly through the body virtually unchanged."[182] Note the qualification. By its own estimates, McNeil believes that fifteen percent of the sucralose humans ingest is absorbed into the body.[183] Apparently to McNeil, "virtually unchanged" is equivalent to a significant rate of absorption. Let's give McNeil the benefit of the doubt. Perhaps it meant that fifteen percent of a single dose of sucralose is "virtually" negligible. Unfortunately, this fails to account for the fact that people will be consuming multiple servings of sucralose every day for years. Is fifteen percent over a lifetime really insignificant? Until long-term human studies have been conducted, we won't know the answer for certain.[184] Until then, I ask you to consider whether a corporation that has repeatedly deceived consumers really views public health as a top priority.

D. Stevia

In the previous sections, we examined how pharmaceutical companies can push their unsafe products through the FDA approval process. This section is even more alarming. It demonstrates how powerful corporations can prevent safe, natural products from obtaining FDA approval. The FDA's treatment of stevia provides the clearest example of how the agency's decisions are made to maximize corporate profits and have nothing to do with science or consumer health. However, before we explore the extent of this corruption, let's briefly look at why this herb is a threat to the artificial sweetener industry.

Stevia is a natural, non-caloric sweetener derived from the South American plant Stevia rebaudiana Bertoni. When refined

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181. *Id.*

182. All About Sucralose, http://www.sucralose.org/facts/brochure.asp (last visited Apr. 8, 2010).

183. *See* B.A. John et al., *The Pharmacokinetics and Metabolism of Sucralose in the Mouse*, 38 FOOD & CHEM. TOXIC. S107 (2000). The FDA estimates that between eleven and twenty-seven percent is absorbed. Food Additives Permitted For Direct Addition to Food for Human Consumption; Sucralose, 63 FED. REG. 16, 417, 16419 (Apr. 3, 1998).

184. *See* Betty Kovacs, Artificial Sweeteners, http://www.medicinenet.com/ artificial_sweeteners/page9.htm (last visited Apr. 8, 2010) (stating that "the only way to be sure of the safety of sucralose is to have long-term studies on humans done").

into a white powder extract, stevia is approximately 300 times sweeter than sugar.[185]

Unlike artificial sweeteners, independent clinical studies have confirmed that stevia is not toxic.[186] The earliest safety study was conducted in 1931, and since then, the findings have been reaffirmed by multiple experiments. In that first study, the researchers determined that humans cannot digest stevia. Unlike McNeil's sucralose trials, this study did not need to qualify its findings with words like "virtually" or "almost." Stevia passes through our bodies completely unchanged.

During the 1970s, while stevia was going through the approval process in Japan, many Japanese scientists conducted additional tests. These trials uniformly indicated that the sweetener is safe for human consumption.[187] Since that time, stevia has been widely used in Japan, Australia, New Zealand, and Switzerland with no ill effects. In Japan, stevia became so popular that, at one point, 1700 tons were consumed annually,[188] accounting for forty percent of the sweetener market.[189] More recent studies have once again confirmed stevia's safety.[190] It bears emphasizing that, unlike the artificial sweetener safety tests, these trials were independently funded.

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185. *See* David Richard, Questions & Answers about Stevia, http://www.stevia.com/Stevia_Article.aspx?Id=2269 (last visited Apr. 8, 2010).

186. *See e.g.*, H. Fujita & T. Edahiro, *Safety and utilization of stevia sweetener*, 22 THE FOOD INDUSTRY 1, 1-8 (1979); IKHLAS A. KHAN & EHAB A. ABOURASHED, LEUNGS ENCYCLOPEDIA OF COMMON NATURAL INGREDIENTS: USED IN FOOD, DRUGS AND COSMETICS 577 (2009) ("Subacute toxicity studies on rats over a 50-day period up to 7.0% concentration of stevioside in feed produced no remarkable toxic effects.").

187. *See e.g.*, H. Akashi & Y. Yokoyama, *Dried Leaf Extracts of Stevia: Toxicological Test*, 18 J. JAPANESE SOC. FOOD SCI. & TECH. 34, 34-43 (1975); H. Fujita & T. Edahiro, 22 J. JAPANESE SOC. FOOD SCI. & TECH. 66 (1979).

188. *See* IKHLAS A. KHAN & EHAB A. ABOURASHED, LEUNGS ENCYCLOPEDIA OF COMMON NATURAL INGREDIENTS: USED IN FOOD, DRUGS AND COSMETICS 577 (2009) (citing M. BLUMENTHAL, WHOLE FOODS 29 (1992)).

189. "[F]ood manufacturers there began using Stevia extracts to sweeten everything from sweet soy sauce and pickles to Diet Coke. Stevia and its extracts have since captured more than 40 percent of the Japanese sweetener market." Herbal Advantage, Stevia - the 'Herbal Advantage' Over Sugar (and its Substitutes), http://www.stevia-products.com (last visited Apr. 8, 2010).

190. *See* K. Toyoda et al., *Assessment of the Carcinogenicity of Stevioside in F344 Rats*, 35 FOOD & CHEM. TOXIC. 597, 597-603 (1997) (concluding "that stevioside is not carcinogenic in rats under the experimental conditions described"); for a review of additional studies, see RAY SAHELIAN & DONNA GATES, THE STEVIA COOKBOOK 28-31 ("[R]esearchers determined that giving laboratory rats 550 mg/kg of stevioside every day for two years did not cause any abnormalities.").

At one point, upon reviewing the literature on stevia, one researcher noted the following:

> Few substances have ever yielded such consistently negative results in toxicity trials as have stevia. Almost every toxicity test imaginable has been performed on stevia extract [concentrate] or stevioside at one time or another. The results are always negative. No abnormalities in weight change, food intake, cell or membrane characteristics, enzyme and substrate utilization, or chromosome characteristics. No cancer, no birth defects, no acute and no chronic untoward effects. Nothing.[191]

Perhaps the best proof of stevia's safety, however, is that it has been consumed, with no adverse effects, for more than fifteen hundred years by the indigenous people of South America.[192] In fact, the Guaraní tribes of Paraguay, Brazil, and Bolivia have long used stevia to lower blood sugar[193] and treat heartburn and hypertension.[194] Recent research has corroborated stevia's medicinal properties.[195] Additionally, since stevia is an excellent source of the antioxidant superoxide dismutase, the herb may also reduce the risk of cancer.[196] Not only is stevia safe, it actually has health benefits, something no artificial sweetener can claim.

The interesting part is that the FDA should have approved stevia even without this safety evidence. The Federal Food, Drug, and

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191. James May, Stevia - Sweetener of Choice for Future Generations, http://www.stevia.com/Stevia_Article.aspx?Id=2413 (last visited Apr. 8, 2010) (quoting Daniel Mowrey).

192. *See* MERCOLA, *supra* note 1, at 205.

193. *Id.*

194. *See* Ashraf Tanvir, Sugar Leaf - A New Breed of 'Sweetener', http://www.parc.gov.pk/articles/sugar_leaf.htm (last visited Apr. 8, 2010).

195. *See* M.H. Hsieh et al., *Efficacy and Tolerability of Oral Stevioside in Patients with Mild Essential Hypertension: A Two-Year, Randomized, Placebo-Controlled Study* 25 CLINICAL THERAPY 2797, 2798 (2003) ("In this 2-year study in Chinese patients with mild hypertension, oral stevioside significantly decreased SBP and DBP compared with placebo. QOL was improved, and no significant adverse effects were noted."); *see* R. Curi et al., *Effect of Stevia Rebaudiana on Glucose Tolerance in Normal Adult Humans*, 19 BRAZ. J. MED. BIO. RES. 771, 771 (1986) (finding that "[t]he extract of Stevia rebaudiana increased glucose tolerance [and] significantly decreased plasma glucose levels during the test and after overnight fasting in all volunteers"); *see* J.O. Atteh et al., *Evaluation of Supplementary Stevia (Stevia Rebaudiana, Bertoni) Leaves and Stevioside in Broiler Diets: Effects on Feed Intake, Nutrient Metabolism, Blood Parameters and Growth Performance*, 92 J. ANIMAL PHYSIOLOGY & ANIMAL NUTRITION 640, 646–47 (2008) (finding that stevia leaves reduced blood levels of glucose, triglycerides and triiodothyronine).

196. *See* S. Ghanta et al., *Oxidative DNA Damage Preventive Activity and Antioxidant Potential of Stevia Rebaudiana (Bertoni) Bertoni, a Natural Sweetener*, 65 J. AGRICULTURAL & FOOD CHEM. 10962, 10962 (2007) (concluding "that *Stevia rebaudiana* may be useful as a potential source of natural antioxidants").

Cosmetic Act has a carve-out for food additives Generally Recognized as Safe (GRAS). The statute provides that the FDA has no regulatory power over any "substance used in food prior to January 1, 1958, [that is determined] through either scientific procedures or *experience based on common use in food* to be safe under the conditions of its intended use."[197] As already noted, stevia had been used for more than a millennium in South America. In addition, prior to 1958, the sweetener had been commonly used in the United States.

Nevertheless, this did not stop the FDA from banning stevia in 1991 to satisfy an anonymous trade complaint.[198] After nearly twenty years and numerous Freedom of Information Act requests, the FDA has steadfastly refused to release the name of the company that requested the ban. These suspicious circumstances led Arizona congressman Jon Kyl to conclude that the FDA's stevia ban is "a restraint of trade to benefit the artificial sweetener industry."[199] Evidence for this claim has mounted in recent years.

In 1992, the American Herbal Products Association submitted a petition to the FDA requesting that stevia be granted GRAS status. The introduction to the petition states that "various extract forms of stevia have been extensively studied and tested. These tests include acute, sub-acute, carcinogenic evaluation and mutagenicity studies. These scientific data . . . demonstrate cumulatively that there is no safety problem associated with the use of an extract of stevia. It appears to be extraordinarily safe."[200] The GRAS affirmation petition went on to cite over 900 articles dealing with stevia, and not a single one reported any adverse health effects.[201]

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197. 21 U.S.C. 321, §201(s).

198. *See* FDA, Import Alert No. 45-06 (May 17, 1991).

199. Healthy News Service, *FDA Continues Pushing Natural Herb Sweetener Stevia Out of U.S.*, http://stevia.com/Stevia_article/FDA_Continues_Pushing_Natural_Herb_ Sweetener_Stevia_Out_of_US/8134 (last visited Feb. 26, 2010) (quoting a 1993 letter from John Kyl to former FDA Commissioner David Kessler).

200. *Id.*

201. *Id.* (A 1995 supplement to the petition indicates that "[t]he petition cites over 120 articles about stevia written before 1958, and over 900 articles published to date. In this well-chronicled history of stevia, no author has ever reported any adverse human health consequences associated with consumption of stevia leaf." The petition itself states "Stevia leaf is a natural product that has been used for at least 400 years as a food product, principally as a sweetener or other flavoring agent. None of this common usage in foods has indicated any evidence of a safety problem. There are no reports of any government agency in any of the above countries indicating any public health concern whatsoever in connection with the use of stevia in foods.").

Despite this overwhelming evidence, the FDA refused to act until Congress forced its hand in 1994. That year, Congress passed the Dietary Supplement and Health Education Act.[202] This law prevented the FDA from regulating any dietary supplement unless it was proven unsafe. Because studies did not attribute any health risks to stevia, the FDA was forced to allow manufacturers to market the herb as a dietary supplement. The agency, however, still refused to approve stevia for use as a sweetener.

Due to the strict regulations regarding the labeling, marketing, and sales of dietary supplements,[203] many consumers still wanted the partial ban lifted. In spite of public support for stevia,[204] the FDA refused to grant approval. At one point, the FDA claimed its concerns were largely based on the work of Mauro Alvarez.[205] Upon learning of this, Alvarez wrote that the FDA had clearly misinterpreted his research:

> [T]he only possible way to report that the results showed detrimental effects is by taking information out of context. If this is the case, one concludes that these FDA scientists are incompetent and irresponsible, or if not, they must belong to some sort of conspiracy group to carry on a sinister agenda against this plant with the objective to keep it away from American consumers by attributing to it safety issues that do not exist.[206]

Nevertheless, for more than a decade, the FDA stuck to the bizarre position that stevia was a safe "dietary supplement" but a toxic "food additive."[207] Never mind the fact that stevia could legally be added to foods in the exact same manner as a food additive so long

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202. Dietary Supplement and Health Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

203. *See* Cooking with Stevia, The FDA and the 1st Amendment or Why The Book Cooking With Stevia Was Banned!, http://www.cookingwithstevia.com (last visited Apr. 7, 2010) ("Simply suggesting that the stevia be mixed with water could be construed as mislabeling and force a recall of the products.").

204. Recall that the FDA refused to ban saccharin because it would upset some consumers. Apparently, consumer support only matters when it aligns with corporate profits. *See* note 95 and accompanying text.

205. Stevia.net, The 19 Studies, http://www.stevia.net/19studies.htm (last visited Apr. 7, 2010).

206. Letter from Mauro Alvarez, Professor, Parque Tecnologico Agro-Industrial do Oeste (Jan. 19, 1998) *available at* http://www.stevia.net/19studies.htm.

207. Many have attributed stevia's paradoxical state to the power of big business. *See e.g.*, Alexandra Marks, *Bitter Dispute Over All-Natural Sweetener*, CHRISTIAN SCI. MONITOR, Sept. 1, 1999, at 2, *available at* http://www.csmonitor.com/1999/0901/p2s1.html ("They say it's safe as long as you use it as a dietary supplement, but if you try to use it as a food it's unsafe? The battle goes back to influence on the FDA from the artificial sweetener industry." (quoting James Kirkland, author of The Stevia Cookbook)).

as the product was labeled a "dietary supplement."[208] These strict supplement regulations, however, did have several important effects. They made major grocery chains reluctant to carry the herb, relegating the sale of stevia to health food stores. This ensured that the vast majority of consumers were unaware of stevia and, in doing so, preserved the market share of artificial sweeteners. For these reasons, the FDA's partial ban could not have been due to safety concerns. It was done purely for economic profit. Remember, in the FDA's view, corporate health comes before consumer health.

Then suddenly, in 2008, the FDA had a change of heart and began allowing stevia to be marketed as a sweetener. What could engender this reversal? Had a new conclusive scientific study been published? Nope, merely the players supporting stevia had changed. In May 2008, Cargill, Merisant, Coca-Cola, and Pepsi submitted petitions to the FDA asking that stevia be granted GRAS approval. For the past two decades, the FDA had denied the exact same requests from consumer groups. However, now that major corporations were behind stevia, the FDA decided it must be safe for consumption. It seems like corporate backing and not science dictates safety. Maybe if corporations wished hard enough, cigarettes would magically become safe, too?[209]

At any rate, in order to fully appreciate the FDA's reversal, one must understand the companies behind the petitions. Merisant is the maker of aspartame-based Equal. Due to the rising popularity of sucralose, Merisant's share of the artificial sweetener market had declined substantially. In fact, sales had fallen so much that the company was pushed into bankruptcy.[210]

Since sucralose had become the dream artificial sweetener in terms of taste and usability, Merisant needed a completely new approach if it hoped to return to profitability. The company ultimately decided to capitalize on the natural and organic trends that are spreading across America. This meant finding a natural product

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208. *See e.g.*, Erica Orden, *Calorie-Free, Stevia's 11-Year War with FDA*, Newsday, May 2, 2006, available at http://www.steaz.com/pdf/news_2006/Newsday0506.pdf. "In January 2004, Steaz, a Pennsylvania-based natural soda manufacturer, introduced a diet line made with stevia rather than aspartame or Nutrasweet. To comply with the legal guidelines, the company can't market it as a soda or even as a beverage (it calls the product a dietary supplement) and must list 'supplement facts' rather than 'nutrition facts' on its back label.

209. *See generally* MICHAELS, *supra* note 12, at 3–11.

210. *See* Chelsea Emery et. al., *Merisant, Maker of Equal, Gets $20 mln DIP Financing*, REUTERS, http://in.reuters.com/article/privateEquity/idINN1232403220090112 (last visited Apr. 12, 2010).

that could compete with sucralose. Lo and behold, stevia was the perfect candidate. Merisant developed a stevia-based sweetener called PureVia[211] and teamed up with Pepsi to market a line of diet soft drinks.[212]

Cargill followed a somewhat similar path. Although it is America's largest agricultural corporation,[213] it had never entered the artificial sweetener market. Like Merisant, Cargill saw that the trend was moving towards natural products. Therefore, it developed Truvia,[214] another stevia-based sweetener, and teamed up with Coca-Cola to produce diet soft drinks.[215]

At this point, there was still one minor problem. The FDA had consistently claimed that stevia was not safe for humans. But with four major corporations now backing stevia (Coca-Cola, Pepsi, Cargill, and Merisant), the agency's stance quickly changed.

As previously noted, these corporations asked that stevia be given GRAS approval in May of 2008. The FDA handled this request in an extremely clever way. Instead of granting GRAS approval which would have allowed every company to use the sweetener, the FDA issued a letter of "no objection."[216] This means that the FDA does not object now, but it may object later. Essentially, the FDA has reserved the right to selectively target companies. Although it has not yet done so, the FDA can allow Coca-Cola and Pepsi to market stevia while preventing smaller companies from producing the sweetener.[217]

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211. PureVia contains the following ingredients: erythritol, isomaltulose, stevia extract, cellulose powder, and natural flavors. Lynn Smythe, Zero Calorie Stevia Sweeteners, http://spices.suite101.com/article.cfm/zero_calorie_stevia_sweeteners (last visited Apr. 12, 2010).

212. Betsy McKay, *FDA Clears Use of Herb As Sweetener*, WALL ST. J., Dec. 18, 2008, at B3.

213. Andrea D. Murphy & John J. Ray, America's Largest Private Companies, http://www.forbes.com/2009/10/28/largest-private-companies-business-private-companies-09_land.html (last visited Apr. 12, 2010) (listing Cargill as #1 with revenue of $106.3 billion);

214. Truvia contains the following ingredients: stevia extract, erythritol, and natural flavors. Smythe, *supra* note 211.

215. Cargill, Honestly Sweet, http://www.cargill.com/connections/more-stories/truvia-natural-sweetener/index.jsp (last visited Aug. 6, 2010).

216. McKay, *supra* note 212; *see* Mike Adams, FDA Approves Stevia, Ends the Era of Oppression of this Herbal Sweetener - Update 1, http://www.naturalnews.com/News_000626_stevia_Truvia_FDA.html (last visited Apr. 12, 2010) (stating that the FDA's issuance of "no objection" letters really means "the FDA hasn't technically granted approval to stevia but has affirmed it will not object to companies using it in foods and beverages.").

217. *See* Adams, *supra* note 216.

Over the past twenty years, stevia has had quite the adventure. One commentator sums up the sweetener's history quite nicely:

> When stevia threatened the profits of aspartame, it was routinely suppressed by the agency. FDA thugs seized imports of stevia at the border, destroyed millions of dollars in stevia products, threatened companies with fines for daring to sell stevia, and even ordered one company to destroy its recipe books that mentioned stevia in dessert recipes. But now, when Coca-Cola and Pepsi want stevia approved, the FDA suddenly reverses its oppression and decides to legalize the herb.[218]

Although stevia's use as a food additive benefits Americans, the process by which it was approved presents a disturbing picture. Corporations routinely manipulate the FDA to maximize profits. If a product hurts the bottom line, the FDA bans it. If it helps the bottom line, the FDA approves it. Science and safety are irrelevant. Obviously, fundamental change is needed.[219] Minor tweaks will only whitewash the problem. Industry must no longer be permitted to corrupt the FDA. The final part of this Article presents two major reforms that can provide the change we need.

III. TAKING INDUSTRY OUT OF THE FDA

Senator Charles Grassley plainly identified the problem when he said that the FDA "needs to reestablish its relationship with its own scientists and distance itself from the drug industry. The FDA needs to get rid of its mind-set that it's a facilitator for the drug industry and become regulator once again. The FDA's focus should be only on science and the public good."[220]

The first section describes the current FDA approval process. The final two sections present reforms that will take industry out of the FDA and ensure that the agency adheres to its mission of "protecting the public health," not filling the corporate coffers.[221]

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218. *Id.*

219. *See* H.R. REP. NO. 104-436, at 12-13 (1995) ("Manipulation of the food additive review process for anti-competitive purposes is inconsistent with the purposes of premarket review.")

220. Jonathan D. Rockoff, *FDA Scientists Report Their Safety Concerns in Poll*, L.A. TIMES, July 21, 2006, *available at* http://articles.latimes.com/2006/jul/21/nation/na-fda21.

221. FDA, *supra* note 9.

A. FDA Approval Process

After a pharmaceutical company develops a drug,[222] it conducts preclinical testing in laboratory animals. Next, the company submits its results to the FDA in the form of an Investigational New Drug Application (IND). By examining the IND, the FDA determines whether it is safe for the drug company to begin testing on humans.

If the FDA approves the IND, the pharmaceutical company can begin the first of three clinical stages. Phase one studies generally use small sample sizes and are conducted on healthy volunteers. The main objective is to identify common side effects and determine how humans absorb and excrete the drug.

The FDA reviews these results and allows the corporation to move onto phase two if the product does not appear unacceptably dangerous. The corporation's goal in phase two is to prove effectiveness. These studies use a moderate sample size (up to 300 participants). To determine if the drug works, subjects in the test group are given the new drug and subjects in the control group are given a placebo or a different FDA-approved drug.

If the corporation can provide evidence of the drug's efficacy, the FDA allows phase three to begin. In this final phase, the pharmaceutical company conducts large-scale tests with up to 3,000 subjects. The purpose of this phase is to check the drug's safety and effectiveness in different populations and at different dosages.

After phase three, the drug company submits a New Drug Application to the FDA. This report should contain all of the data and results gathered during the previous tests. However, as evidenced most prominently by G.D. Searle's aspartame reports, damning data is often withheld.

The FDA forms a review team consisting of medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts to evaluate whether the drug company's trials show conclusive evidence of safety and effectiveness. At times, the FDA calls on advisory committees for help. Finally, higher level directors determine whether the drug should be approved.[223]

At first glance, this appears to be a relatively sound approval process. However, there are two major flaws that should make Americans question the reliability of the FDA's conclusions. First, due to their close financial ties to the businesses they are regulat-

222. Food additives undergo a similar but less rigorous process.

223. For a more detailed explanation of the process, *see* FDA, *supra* note 11.

ing,[224] the people making the final decisions are often guided more by politics than scientific analysis.[225] This is particularly true of top directors and commissioners who often leave the FDA and join pharmaceutical companies or lobbying firms for especially lucrative salaries.[226] As a remedy to this problem, the next section will propose life tenure and strengthened conflict-of-interest regulations.

The second major flaw in the current approval process is that pharmaceutical companies conduct the studies to determine their own products' safety and effectiveness. Since drug companies only care about profit maximization, they are not concerned with accurately assessing a product's health risks. This has caused the industry to employ countless deceptive strategies to trick the FDA and the general public into believing that toxic chemicals are actually safe. To guarantee that the FDA's decisions are based on valid data, the final section advocates adopting a system that takes industry out of science.

B. Locking the Revolving Door

Currently, thirty-six percent of FDA scientists feel they cannot express "concerns about public health without fear of retaliation."[227] Since more than one-third of researchers are afraid to do their jobs, the FDA obviously needs to reform its entire culture.

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224. *See* Andrew Bridges, Ex-FDA Chief Pleads Guilty in Stock Case, THE WASH. POST, Oct. 17, 2006, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/10/17/AR2006101700573.html ("Former FDA Commissioner Lester Crawford pleaded guilty Tuesday to conflict of interest and false reporting of information about stocks he owned in food, beverage and medical device companies he was in charge of regulating.").

225. Union of Concerned Scientists, *supra* note 5, at 3 (quoting a scientist from the Center of Devices and Radiological Health as saying "In my experience, it is never the 'low level' reviewers in the FDA who breach the integrity of our work. It is usually at much higher levels, such as center directors and above. Those higher levels are so far removed from the scientific work we do that politics has even more sway over their decisions.").

226. The FDA's revolving door is well documented. *See e.g.*, Mike Palmedo, Revolving Door Between the U.S. Government and Industry, http://www.cptech.org/ip/health/politics/revolvingdoor.html (last visited Apr. 12, 2010); Jennifer Ferrara, *Revolving Doors: Monsanto and the Regulators*, 28 THE ECOLOGIST 280, 280–87 (1998); Policy Directions Inc., Professionals: Lester M. Crawford, DVM, PhD, Senior Science Advisor, http://www.policydirections.com/professionals.php?queue=crawford (last visited Apr. 12, 2010) (Former FDA Commissioner Lester Crawford is now working for a Washington lobbying firm, Policy Directions Inc.).

227. Union of Concerned Scientists, *supra* note 5, at 3.

Agency scientists have made it clear that any solution should start with high level directors.[228] Therefore, the new system must focus on developing a culture of independence at the top. For our purposes, the top means the FDA Commissioner and the forty-eight advisory committees.

In order to create an independent agency, all conflicts of interest must first be eliminated. "A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)."[229] Because even the smallest secondary ties can create undue influence,[230] committee members must be completely removed from the industries they will be regulating.

In theory, each committee should consist of independent experts who advise the agency on product safety and effectiveness.[231] Recognizing that an extremely important requirement is independence, federal law already forbids anyone with a conflict of interest from serving on an advisory committee.[232] However, given the ease with which waivers are granted, this prohibition has become meaningless.[233]

The FDA published a whopping twenty-two page document for determining a conflict of interest.[234] Despite these lengthy rules,

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228. *Id.* at 2, ("Less than half (44 percent) say they 'respect the integrity and professionalism of FDA leadership.'").

229. Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993).

230. *See generally*, JEROME P. KASSIRER, ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH 1–24 (2005) (describing how even insignificant gifts like pens and coffee mugs can create a conflict of interest that influences doctors).

231. *See* Food and Drug Administration, Advisory Committees, http://www.fda.gov/AdvisoryCommittees/default.htm (last visited Feb. 26, 2010) (The FDA "uses 48 committees and panels to obtain *independent* expert advice on scientific, technical, and policy matters." (emphasis added)).

232. *See* Food and Drug Administration, *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (2008), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf.

233. *See* MERCOLA, *supra* note 1, at 163 ("[B]etween 1998 and 2000, the FDA waived [the conflict of interest] restriction more than 800 times.").

234. *See* Food and Drug Administration, *Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (2007), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0101-gdl0001.pdf.

"doctors who earn hundreds of thousands of dollars each year in 'consulting fees' from drug companies are not only allowed to vote on the recommendations for FDA approval of their drugs, there is not even any FDA requirement to disclose such conflicts of interest."[235] Instead of complex guidelines, the agency could use a straightforward one-sentence test: Within the past five years, have you or your immediate family had financial ties to the industry you will be regulating? If the answer is yes, the person is disqualified, regardless of expertise. Financial ties would include more than monetary compensation. Any sort of remuneration would preclude someone from serving in a top level position. This is a necessary measure so that corporations do not influence experts with vacations, televisions, cars, meals, or other incentives.

So where do we get enough pure souls to staff the FDA committees? After all, more than half of the current advisory committees have financial ties to the companies they are regulating.[236] This is a troubling statistic, but there is a bit of hope contained within it. Nearly half of the advisory committees did not have financial conflicts of interest. Since the FDA can currently staff almost half of its panels with independent experts, there is no reason it cannot fill all of its panels with such people. Although this Article has painted a stark picture, the vast majority of scientists at the FDA are committed to protecting the public health. Therefore, promoting from within is one viable option.

Because only the FDA commissioner and the committee members will be subject to the five year regulation, people with recent ties to industry will still be able to work at the FDA. However, by barring them from immediately taking high-level positions, the culture of the agency will change. This top-down approach will foster a sense of independence within the FDA. It will also allow low level scientists to do their job without fear of retribution from their superiors. No longer will the FDA and corporations be partners in a quest for greater profits.

Another option is to recruit scientists from universities. Admittedly, industry has tainted medical schools, but in recent years, many have committed to regaining independence. This past year, Harvard Medical School strengthened its conflict of interest regulations,

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235. Mike Adams, Americans Fed up with Drug Industry Influence, FDA Corruption, Reveals Remarkable Consumer Reports Survey, http://www.naturalnews.com/021795.html (last visited Apr. 12, 2010).

236. *See* MERCOLA, *supra* note 1, at 163.

and other schools have followed suit.[237] Trade organizations have pressured other schools to make similar policy changes. The Association of American Medical Colleges views connections between researchers and industry as a "peril to academic medicine and public health."[238] The American Medical Student Association now rates schools based on their conflict of interest policies. In 2008, just eight schools obtained an "A" ranking.[239] In 2009, that number increased to twelve, with forty-seven other schools earning a "B" ranking.[240] As universities continue their reforms, they will become an even better resource for the FDA.

Now that we have identified our candidate pool, how does the FDA make its selection? Because the judiciary is the most trusted branch,[241] it serves as a good model for FDA committees. To begin, an oversight committee should be created. The members of this panel should be granted life tenure. They shall be appointed by the President and confirmed by the Senate.

When vacancies need to be filled on any of the forty-eight subcommittees, the FDA commissioner will nominate a candidate and the oversight committee will approve or reject the nomination. When a new drug or food additive application is submitted, the appropriate subcommittee will review the available studies and make a recommendation. The oversight committee will have the final say

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237. *See* Liz Kowalczyk, Harvard Will Stiffen Rules for Staff at Med School, BOSTON GLOBE, Feb. 3, 2009, *available at* http://www.boston.com/news/local/massachusetts/articles/2009/02/03/harvard_will_stiffen_rules_for_staff_at_med_school (last visited Feb. 26, 2010) ("Many top medical schools, including Stanford University, the University of Pennsylvania, the University of California at Los Angeles and at San Francisco, and the University of Massachusetts have adopted stricter policies in the past two years.").

238. Susan Ehringhaus & David Korn, *Conflicts of Interest in Human Subjects Research*, ISSUES IN SCIENCE AND TECHNOLOGIES (Winter 2002), *available at* http://www.issues.org/19.2/ehringhaus.htm (last visited Apr. 7, 2010).

239. Dane Secor, *AAMC Joins Movement to Restrict Pharmaceutical Company-Physician Relationships*, 6 ACAD. INTERNAL MED. INSIGHT 6 (2008) ("Only eight out of the approximately 150 medical schools surveyed received an 'A,' which indicates the institution has strong policies that address conflicts of interest caused by pharmaceutical industry marketing.").

240. *See* AMERICAN MEDICAL STUDENT ASSOCIATION, CONFLICT OF INTEREST POLICIES AT ACADEMIC MEDICAL CENTERS, http://www.amsascorecard.org (last visited Apr. 7, 2010).

241. *See generally* Frank Newport, Americans' Trust in Legislative Branch at Record Low, GALLUP, Sept. 10, 2009, http://www.gallup.com/poll/122897/americans-trust-legislative-branch-record-low.aspx (Since 1974, Americans have trusted the judiciary more than the executive or legislative branches.).

on all applications, but great deference should be given to the decision of the subcommittees.

For five years after stepping down, the FDA commissioner and committee members will be unable to accept any compensation from a regulated industry. This is a necessary measure to prevent corporations from making promises of future gain to entice regulators to approve a drug or food additive. This is not an unfamiliar proposal, but its enforcement would be novel. In the past, Presidents have placed similar restrictions on some of their appointees. Unfortunately, they have merely served as talking points rather than stringent policies.[242]

The proposal does not provide for a perfect selection mechanism, but any effective system will inevitably produce false positives. If the policy is overly restrictive, we can rest assured that it is much better to exclude too many people than to permit those with bad intentions to control the FDA.

The most common argument in favor of the revolving door is that industry consultants are the only people with sufficient expertise to evaluate the latest drugs. Jerome P. Kassirer, the former Editor-in-Chief of the *New England Journal of Medicine*, calls this claim the "fallacy of unique expertise."[243] He argues that we should not need to rely on conflicted experts because independent scientists quickly develop the necessary skills.[244] In fact, relying on industry experts may be detrimental for reasons beyond the obvious conflict of interest. When people with similar views come together, they are subject to group polarization.[245] Because the industry experts are already sympathetic to pharmaceutical companies, this bias will be amplified when they try to reach a group consensus.[246]

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242. President Clinton enacted a measure that prevented certain appointees from working in regulated industry. In the last days of his presidency, he repealed the measure. Likewise, President Obama's restrictions are set to expire at the end of his presidency.

243. KASSIRER, *supra* note 230, at 204.

244. *See id.* at 204–05 ("[N]obody has provided any evidence that people with financial ties to industry are better in assessing evidence on any a particular subject than those without such ties . . . . There is no fundamental reason to think that such panels of intelligent clinicians who have no industry connections would be unable to assess a body of clinical data and arrive at useful recommendations.").

245. *See generally*, Cass Sunstein, *The Law of Group Polarization* 1–15 (John M. Olin Law & Econ., Working Paper No. 91, 1999), *available at* www.law.vchicago.edu/Files/Files/91.CRS_.Polarization.pdf.

246. *See* KASSIRER, *supra* note 230, at 205 ("[T]here is real risk that like-minded people with 'unique' knowledge may have similarities of thought and come up with a uniform conclusion that is biased (or even completely wrong).").

Even if one concedes that industry scientists are the most qualified experts, this argument ignores a more fundamental issue. The FDA will make better decisions if it is run by good, independent scientists than if it is run by excellent, corrupt scientists. Nonetheless, as discussed above, there is no reason to believe that the FDA will be unable to staff its committees with excellent, independent scientists.

Now that we have setup independent committees, the next step is to determine what standard they should apply when approving new substances. It is clear that the FDA must presume a product is unsafe until studies show otherwise,[247] so three possibilities jump to mind: preponderance of the evidence,[248] clear and convincing evidence,[249] and beyond a reasonable doubt.[250] In choosing a standard, our goal should be to build in a margin of safety without unduly restricting food and drugs from reaching the market.

For this reason, I think it is fair to rule out preponderance of the evidence. If the committee determines it is only slightly more probable than fifty percent that the food or drug is safe, it should deny the application. On balance, it is better to reject a product that is harmless than approve a product that is dangerous. After all, the rejected substance can undergo additional tests to better ascertain

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247. The law already provides for this presumption, even though recent history seems to indicate that the FDA presumes a substance is safe until proven otherwise. *See* 21 U.S.C. § 348(c)(3)(A) ("No such regulation shall issue if a fair evaluation of the data before the Secretary–fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe . . . .").

248. *See* Neil Orloff & Jery Stedinger, *A Framework for Evaluating the Preponderance-of-the-Evidence Standard*, 131 U. PA. L. REV. 1159, 1159 (1983) (noting that the traditional preponderance of the evidence standard "requires demonstrating that the existence of the contested fact is more probable than its nonexistence").

249. BLACK'S LAW DICTIONARY 596 (8th ed. 2004) (defining clear and convincing evidence as "evidence indicating that the thing to be proved is highly probable or reasonably certain. This is a greater burden than preponderance of the evidence, the standard applied in most civil trials, but less than evidence beyond a reasonable doubt, the norm for criminal trials.").

250. BLACK'S LAW DICTIONARY 1293 (8th ed. 2004) (quoting Commonwealth v. Webster, 59 Mass. (5 Cush.) 295, 320 (1850)) (defining reasonable doubt as "a term often used, probably pretty well understood, but not easily defined. It is not a mere possible doubt; because every thing relating to human affairs, and depending on moral evidence, is open to some possible or imaginary doubt. It is that state of the case, which, after the entire comparison and consideration of all the evidence, leaves the minds of jurors in that condition that they cannot say they feel an abiding conviction, to a moral certainty, of the truth of the charge.").

its safety, but once the toxic food or drug enters the market, the damage is done.

The more difficult decision involves choosing between clear and convincing evidence and beyond a reasonable doubt. They both prove useful in their own way.

At present, food additives require less rigorous testing than drugs. This is backwards. Although it may seem counterintuitive at first, the standard required to approve food additives should be higher than drugs. Accordingly, I recommend using the beyond a reasonable doubt standard for food additives and the clear and convincing evidence standard for drugs.

Food additives are generally marketed on a national scale and included in many products. Due to the sheer number of options, most people do not know which products contain which additives. Therefore, when someone consumes an additive, it is, with few exceptions, the result of an indirect choice.

For example, no one buys Swedish Fish gummy candies because they want to eat the food dye Red No. 40. People buy the candy because they like the taste. In fact, I would wager that most people who have eaten Swedish Fish never even thought about what food additive is used to make the red coloring. To go one step further, despite the fact that Red No. 40 is the most widely used food coloring,[251] the vast majority of Americans have likely never even considered its safety. FDA approval is such a powerful signal that millions of people are willing to eat food additives everyday just because the FDA says it is okay. The faith is so strong that the average American consumes 150 pounds of food additives each year,[252] ten pounds of which are chemical in nature.[253]

Another argument for a beyond a reasonable doubt standard is that the costs of a false negative are much lower. Rejecting a safe food additive will not lead to deaths or prevent the cure of diseases. On the other hand, denying the application for a safe drug can

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251. The History of Food Dyes, http://www.red40.com/pages/history.html (last visited Apr. 9, 2010). Manufacturers use this orange-red color in all sorts of gelatins, beverages, dairy products and condiments. FDA certified more than 3 million pounds of the dye in fiscal year 1992—almost a million pounds more than the runner-up, FD&C Yellow No. 5. *Id.*

252. DEANNA MINICH, AN A-Z GUIDE TO FOOD ADDITIVES: NEVER EAT WHAT YOU CAN'T PRONOUNCE 10 (2009).

253. *The Myth of Convenience- Which Nutritional Supplement Ingredients May Be Silently Undermining Your Health?*, 1 INTEGRATED SUPPLEMENTS NEWSLETTER 4 (Integrated Supplements), April 2007, at 1, *available at* http://www.integratedsupplements.com/articles/Newsletter200704.pdf.

cause people to die or otherwise reduce their quality of life. Furthermore, although Americans consume more drugs than people in any other nation,[254] the total still pales in comparison to the amount of food additives we consume.

But the principal reason that the FDA should use a clear and convincing evidence standard for drugs is that taking medicine is a concerted choice. Although chemical additives are crammed into nearly every food imaginable, drugs are not. No one buys a different brand of cereal one day only to find out that it is loaded with drugs.

There is also a line of defense between the FDA and the consumer. As experts on medication, doctors are supposed to inform the patient of the side effects and benefits of prescriptions. This process adds a layer of reflection to taking drugs, something that is absent from food additives. For these reasons, the FDA should reverse its policy, and food additives should be held to a higher standard than drugs.

Now that we have laid out an approval process, one key feature is still missing: data. Even if the committee members are independent experts, their decisions can only be as good as the studies they review. Therefore, it is imperative that industry no longer be permitted to participate in the testing process. The following section explores an alternative system that can ensure these new independent FDA committees are only reviewing high quality studies.

C. Taking Industry out of Safety Trials

Pharmaceutical companies are skilled at manipulating data in ways that cast their products in a favorable light. One common tactic is to fund dozens of clinical trials with the expectation that only a few studies will be published.[255] Random chance explains why this is a useful but deceptive strategy. To be accepted by the scientific community, the results of an experiment must be statistically significant at the five percent level. In statistical terms, the p-value must be $\leq .05$. This means that if a drug is no different than a placebo,[256] only five percent of the experiments will have data at least this extreme.

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254. Associated Press, *American's Remain World's Most Medicated People*, ST. PETERSBURG TIMES, April 17, 2005, http://www.sptimes.com/2005/04/17/Worldandnation/Americans_remain_worl.shtml (last visited Feb. 26, 2010).

255. *See* MICHAELS, *supra* note 12, at 150.

256. This is the null hypothesis.

From the pharmaceutical industry's perspective, if a drug is ineffective, ninety five percent of its clinical trials will yield data supporting this conclusion. However, due to random chance, five percent of its trials will still provide evidence that the drug is beneficial. By funding dozens of experiments, corporations are exploiting the test for statistical significance. The drug manufacturer holds back the ninety five percent of trials that show the product's inefficacy.[257] At the same time, it publishes the five percent of trials that attest to the drug's usefulness.[258]

Another common ploy is to truncate data. If a clinical trial lasts for two years and the results show that a given drug is ineffective, industry scientists simply look at smaller chunks of the data. Maybe the trial passes the test for statistical significance during a one year period. Maybe six months is the magic number.[259] If cutting out time doesn't work, the beneficiaries can also be reframed. Instead of using data for the entire population, industry scientists often look at smaller demographics. If the drug doesn't have an effect on Asians, don't worry. Simply drop them from the study. Do Hispanics meet the test for significance? If so, leave them in. When that doesn't work, get more creative. Maybe the magic group is women aged twenty-seven to thirty-two with blue eyes.[260] Never mind that only a couple trial participants may have fallen into this category.

Even more deceptive tactics include fabricating data, discontinuing studies that yield unfavorable results, and excluding individual subjects that develop adverse reactions, such as malignant tumors. When these strategies are insufficient, corporations have

257. Although data for all of the trials is required to be submitted to the FDA, many corporations withhold adverse studies.

258. *See*, Erik H. Turner et al., *Selective Publication of Antidepressant Trials and its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 255 (2008) (Ninety-four percent of the published studies reported positive results, whereas only 51% of the FDA-registered studies had positive results. "Overall, the studies that the FDA judged as positive were approximately 12 times as likely to be published" as neutral or negative studies.); *see also* David S. Liebeskind et al., *Evidence of Publication Bias in Reporting Acute Stroke Clinical Trials*, 67 NEUROLOGY 973, 973 (2006) (concluding that "publication bias is evident in the acute stroke research literature").

259. The drug manufacturer Pharmacia used this strategy to provide evidence that Celebrex reduces the incidence of ulcers. The highly respected *Journal of the American Medical Association* was fooled into publishing this "science." *See* MICHAELS, *supra* note 12, at 150.

260. VaxGen manipulated the data for AidsVax, an AIDS vaccine, in a similarly absurd manner. *See* MICHAELS, *supra* note 12, at 151.

simply ordered their scientists to write favorable reports regardless of the evidence.[261]

The extent of these manipulative practices is easily observed when independent scientists conduct meta-analyses. Although this article has focused on how pharmaceutical companies employed these misleading tactics to gain FDA approval for artificial sweeteners, the problem is much more pervasive. Richard Smith, the Editor-in-Chief of the *British Medical Journal*, has pointed out several other notable examples of industry bias:

> "The major determinant of whether reviews of passive smoking concluded it was harmful was whether the authors had financial ties with tobacco manufacturers. In the disputed topic of whether third-generation contraceptive pills cause an increase in thromboembolic disease, studies funded by the pharmaceutical industry find that they don't, and studies funded by public money find that they do."[262]

This abuse of the scientific process undermines both industry and independent research. It essentially creates a presumption that corporate science is false, going so far as to taint companies that do not engage in deceptive practices. As the junk science piles up, the public is pushed towards a tipping point.[263] When distrust of science reaches this critical mass, it will be extremely hard to convince Americans that scientific results cannot be bought by the highest bidder. The inevitable result is that the public will lose confidence in science as a whole. The first effects of this phenomenon are already being felt.

For example, many parents refuse to vaccinate their children because they do not believe the science that shows vaccines are safe.[264] Fear of industry deception has led to actual problems, such

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261. *See* Keith J. Winstein & David Armstrong, *Top Pain Scientist Fabricated Data in Studies, Hospital Says*, WALL ST. J., Mar. 11, 2009, at A12. (Scott S. Reuben, former chief of acute pain at Baystate Medical Center fabricated data for twenty-one studies involving Vioxx, Celebrex, and Lyrica. Pfizer (maker of Celebrex and Lyrica) funded part of Reuben's research and paid him generous speaking fees.) For additional examples of these tactics, see footnotes 144–149 and accompanying text.

262. Richard Smith, *Making Progress with Competing Interests*, 325 BRIT. MED. J. 1375, 1375–76 (2002).

263. Malcolm Gladwell describes the tipping point as "the moment of critical mass, the threshold, the boiling point." *See* MALCOLM GLADWELL, THE TIPPING POINT: HOW LITTLE THINGS CAN MAKE A BIG DIFFERENCE 12 (2002).

264. *See* Nadja Popovich, *Vaccine Scare Shows How Emotions Can Trump Facts*, NPR http://www.npr.org/blogs/health/2010/02/risky_business_reactions_to_th.html (last visited May 23, 2010).

as an increased incidence of measles.[265] A more salient example involves the H1N1 vaccine.[266] Many people declined to get vaccinations because they believed the pharmaceutical companies were promoting unsafe vaccines.[267] Although the H1N1 virus did not become a major threat, it is easy to envision a scenario in which an actual epidemic breaks out and people refuse to get vaccinated.

The loss of faith in science is not limited to health issues. The polarizing debate over global warming has accentuated the problem.[268] Ralph Cicerone, president of the National Academy of Sciences noted that "[t]here is evidence that the corrosion in the public attitude to climate science has spread over to other areas of science."[269]

The lesson to be learned is that industry-funded science undermines legitimate science. Government agencies must stop using it as a basis for decisions. Given the importance of public health, the FDA, in particular, should only rely on independently funded trials.

With this in mind, an entirely new pre-market approval system must be implemented. There are two options for such a system. First, the FDA could take on the responsibility of conducting the clinical trials. This presents some tangible benefits. For instance, because studies would be done in-house, an intermediate layer of FDA scientists would not need to review the trials. Additionally, as

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265. Rong-Gong Lin II, *Rise in Measles Prompts Concern*, L.A. TIMES, May 2, 2008, *available at* http://articles.latimes.com/2008/may/02/local/me-vaccine2 (last visited May 23, 2010); *see also* BBC News, Rise in Measles 'Very Worrying', http://news.bbc.co.uk/2/hi/health/7872541.stm (last visited May 23, 2010).

266. *See* Paul A. Offit, *Nothing to Fear but the Flu Itself*, N.Y. TIMES, Oct. 12, 2009, at A23, http://www.nytimes.com/2009/10/12/opinion/12offit.html?_r=2&em (last visited May 23, 2010).

267. *Id.*

268. *See* Rasmussen Reports, Americans Skeptical of Science Behind Global Warming, http://www.rasmussenreports.com/public_content/politics/current_events/environment_energy/americans_skeptical_of_science_behind_global_warming (last visited May 23, 2010). A recent poll noted the following:

> Fifty-nine percent (59%) of Americans say it's at least somewhat likely that some scientists have falsified research data to support their own theories and beliefs about global warming. Thirty-five percent (35%) say it's Very Likely. Just 26% say it's not very or not at all likely that some scientists falsified data. This skepticism does not appear to be the result of the recent disclosure of e-mails confirming such data falsification as part of the so-called "Climategate" scandal. *Id.*

269. Clive Cookson, *Public Losing Faith in Science*, FINANCIAL TIMES http://www.ft.com/cms/s/2/1700ab46-1dbc-11df-9e98-00144feab49a.html (last visited May 23, 2010).

the people running the studies and the people making approval decisions would be working within the same agency, communication should be more open. This may lead to better information when questions arise at the top.

On the downside, the federal government is not known for its efficiency.[270] Even if one does not subscribe to this view, a majority of the American people do, and that provides a compelling reason to prevent an FDA expansion. First, the public no longer trusts the federal government.[271] They think it is corrupt and inefficient.[272] The average American believes the federal government wastes half of all its revenues.[273] In addition, a majority of Americans want smaller government.[274] These views have become even more dominant during the current recession.

As another matter, corporate America constitutes a powerful interest group that will oppose any reform of the FDA's regulatory system. An expansion of government would provide powerful am-

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270. Friedrich Hayek nicely sums up a major tenet of classical liberalism, calling the free market a "more efficient allocation of resources than any design could achieve." CHRISTINA PETSOULAS, HAYEK'S LIBERALISM AND ITS ORIGINS: HIS IDEA OF SPONTANEOUS ORDER AND THE SCOTTISH ENLIGHTENMENT 2 (2001).

271. *See* Jason Iuliano, *Eliminating Earmarks: Why the Congressional Line Item Vote can Succeed Where the Presidential Line Item Veto Failed*, 112 W. VA. L. REV. 947, 957–58 (2010); Andy Barr, Poll Finds Low Trust in Feds, http://www.politico.com/news/ stories/0109/17424.html (last visited May 23, 2010) (For example, a recent poll of registered voters found that "[o]nly 5 percent said they have a 'great deal' of trust that the federal government will manage its finances responsibly, while 23 percent expressed 'some' trust that the government will be financially responsible. Meanwhile, an overwhelming 63 percent of respondents described their amount of trust as 'not very much' or 'none at all.'").

272. *See* CNN, *Half of Americans Think Congress is Corrupt*, http://www.cnn.com/2006/POLITICS/10/19/congress.poll/index.html (last visited May 23, 2010).

273. *See* Lydia Saad, Americans: Uncle Sam Wastes 50 Cents on the Dollar, http://www.gallup.com/poll/122951/americans-uncle-sam-wastes-50-cents-dollar.aspx (last visited May 23, 2010) (finding that "Americans believe 50 cents of every tax dollar that goes to the government in Washington, D.C., today are wasted").

274. *See e.g.*, David Boaz, Americans Want Smaller Government, http://www.cato-at-liberty.org/2009/06/23/americans-want-smaller-government (last visited May 23, 2010) (citing a Washington Post-ABC News poll that found Americans prefer smaller government to larger government by a margin of 54 to 41); Rasmussen Reports, National Survey of 1,000 Likely Voters Conducted March 18-19, 2009 http://www.rasmussenreports.com/public_content/politics/toplines/pt_survey_toplines/march_2009/toplines_benchmarks_march_18_19_2009 (last visited May 23, 2010) (finding that 66% of Americans prefer a smaller government with lower taxes and only 25% prefer a larger government with higher taxes).

munition, allowing corporations to mobilize public opposition. Hence, keeping the research process privatized is preferable.

This leads to the second option. The FDA could hire independent universities and clinical research centers[275] (CRCs) to perform the safety trials. This would maximize efficiency, alleviate public concern over government expansion, and still remove conflicts of interest. Since pharmaceutical companies already use CRCs to conduct their safety tests, this may seem like a misguided recommendation. However, the problem with the current system is that it lacks independence. Because CRCs contract directly with corporations, they are unwilling to bite the hand that feeds them. This causes CRCs to rig the data and draw faulty conclusions. If we can insert an intermediary into this process, the CRCs incentives will change. Their goal will no longer be to please the pharmaceutical industry, but rather, to please the intermediary. The FDA can fill this role well.

When a corporation submits a new food or drug to the FDA for approval, the agency will construct the specifications for clinical trials and hold an auction to select the CRC or university lab that will test the new product. The sponsoring corporation will pay the FDA the low bid amount, and the FDA will pass this money along to the winner. The government routinely uses sealed first-price auctions to grant procurement contracts and to lease the mining rights to land,[276] so there is no reason such a system cannot work in this context.

Naturally, not all CRCs and universities will be permitted to bid at the auction. If this were not the case, corporations could simply fund their own CRCs and underbid all the competitors. Instead, only labs with strict conflict of interest policies will be permitted to participate. At present, there are nearly a thousand CRCs, so finding a sufficient number of bidders should be easy. Even if few labs currently meet the FDA's strict standards, a market for independent CRCs will quickly develop. Also, as noted in the preceding section, many universities are tightening their rules regarding conflicts of interest.

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275. The FDA defines a clinical research center as "a person [i.e., a legal person, which may be a corporation] that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration." 21 CFR 312.3(b).

276. *See* R. Preston McAfee & John McMillan, *Auctions and Bidding*, 25 J. ECON. LIT. 699, 702 (1987).

To promote independence, a blind review process should be setup. The corporation should not know which CRC is evaluating its product. Likewise, the CRC should not know which corporation developed the test substance. Due to the number of companies that are researching similar drugs, this should not pose a problem, but even if determined CRCs figure out which corporation's drug they are testing, they have no incentive to act on that information. Because of the conflict of interest rules, their loyalties will lie with the FDA, not the pharmaceutical industry.

When the tests are completed, all data should be made available for public examination.[277] Then the appropriate FDA advisory committee should review the studies and vote to approve or reject the product. Because the advisory committees will be composed of experts in specific fields and will have more time to evaluate individual substances, the oversight committee should grant strong deference to the lower committees' decisions. In judicial terms, the standard of review should be akin to abuse of discretion.

Taken together, these two changes can reform the entire culture of the FDA. No longer will industry be able to control the food and drug approval process.

CONCLUSION

In the last half century, an obesity epidemic has swept across America, leading to a surge in health problems. Excessive sugar consumption has further aggravated this situation. The problem persists because the public wants to both trim its waistline and satisfy its sweet tooth. To fill this market, corporations developed a series of non-caloric artificial sweeteners. It was truly a miracle: hundreds of times sweeter than sugar and none of the calories. Unfortunately, like most things that are too good to be true, artificial sweeteners came with a heavy price. They may not add extra calories to your diet, but they will cause a litany of health issues.

Corporations, which stood to make billions if their products succeeded, hid the dangers of artificial sweeteners from the Ameri-

277. The public overwhelmingly supports this reform. *See* Consumer Reports, Consumer Reports Survey Finds Strong Backing for Drug Reforms, http://www.consumerreports.org/health/prescription-drugs/consumer-reports-survey-finds-strong-backing-for-drug-reforms-4-07/overview/consumer-reports-survey-finds-strong-backing-for-drug-reforms.htm (last visited May 23, 2010) ("Ninety-two percent of Americans agree that pharmaceutical companies should make public the results of all of their clinical trial studies, which reveal a drug's effectiveness as well as possible hazardous side effects.").

can people. Some FDA scientists caught on to this deception and alerted their superiors. Sadly, the decision makers at the FDA had serious conflicts of interest. Like the corporations they were supposed to be regulating, these people would profit greatly if the artificial sweeteners were approved. Quite simply, FDA leaders put their personal welfare above everyone's safety.

If the FDA is to break free of industry control, reform is necessary.[278] First, conflict of interest regulations must be strengthened. The public can only be confident in the FDA's decisions if its leadership does not have ties to corporations. The second proposed change requires hiring independent organizations to conduct the clinical trials. Corporations have repeatedly shown that they will employ deceptive tactics to get their drugs and food additives approved. Because the profit motive has corrupted their ability to perform legitimate studies, corporations should no longer be permitted to participate in the safety and efficacy tests. America's health is too important to trust with conflicted actors. To restore the agency's integrity, industry must be taken out of the FDA.

278. Although this Article focused on the FDA, the recommendations are equally applicable to other government agencies. Even those that have resisted industry capture can benefit by adopting more stringent conflict of interest regulations. The public's perception of the entire government is so poor that every agency has room to improve its image.

NOT COOL: THE CONSEQUENCES OF MANDATORY COUNTRY OF ORIGIN LABELING

Matt Mullins[*]

I. INTRODUCTION

The much anticipated and hotly debated Country-of-Origin Labeling (COOL) provision of the 2002 Farm Bill went into effect on September 30, 2008.[1] The interim final rule published on August 1, 2008 finally put into law a provision first passed in the 2002 farm bill.[2] This provision requires grocery stores and other retailers[3] who sell food products to the private consumer to label certain meats, vegetables, fruits, and nuts with their country of origin.[4] Foods that must be labeled are identified in the bill as "covered commodities."[5] But, for all of the covered commodities, there exists a substantial list of products that do not require the COOL label: "processed food items."[6] The United States Department of Agriculture (USDA), the

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1. Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts, 74 Fed. Reg. 2682 (Jan. 15, 2009) (to be codified at 7 C.F.R. pts.60 and 65) [hereinafter Mandatory COOL].

2. *Id.*

3. *Id.*

4. Mandatory COOL, 74 Fed. Reg. 2682 (Jan. 15, 2009) (to be codified at 7 C.F.R. pts.60 and 65).

5. Geoffrey S. Becker, *CRS Report for Congress: Country of Origin Labeling for Foods*, (May 13, 2008). These covered commodities include the following: muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; perishable agricultural commodities (fresh and frozen fruits and vegetables); macadamia nuts; pecans; ginseng; and peanuts. *Id.*

6. Mandatory COOL, 74 Fed. Reg. 2682 (Jan. 15, 2009) (to be codified at 7 C.F.R. pts.60 and 65) [hereinafter The Final Rule]. The Final Rule defines "processed food item" as a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered

purveyor of the interim final rule, has broadly defined processing to include any item "undergoing a specific processing to change the character of the commodity or combining it with at least one other covered commodity or substantive food component."[7] These exceptions lead to some puzzling distinctions between covered and exempted commodities. For example, raw peanuts would require a label, but roasted peanuts would be exempt since roasting is considered by the rule to be a further processing; pork chops would require a COOL label, but ham and bacon would not require the label; and chopped lettuce in the produce section of the grocery store must be labeled, but chopped lettuce on the salad bar at the grocery store would be exempt under the restaurant exception.[8]

The COOL provision also draws some arbitrary lines between end-retailers that must label and retail establishments that are exempt. The rule imposes the labeling requirements on any retailer whose invoice cost of all purchases of perishable agricultural commodities exceeds $230,000 during a calendar year.[9] Based on a strict reading of the rule, this means that most grocery stores would be required to adhere to the provisions while those operating pure butcher shops would be exempt since their perishable agricultural commodities invoices would not total $230,000 per calendar year.[10]

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commodity, or that has been combined with at least one other covered commodity or other substantive food component (e.g., chocolate, breading, tomato sauce), except that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item. *Id.*

7. Produce Marketing Association, *PMA Analysis: USDA Final Rule for Mandatory Country of Origin Labeling*, http://www.pma.com/issues/COOLAnalysis.cfm (last visited Feb. 20, 2010).

8. Consumer Union's "COOL TOOL": Don't Be Fooled By Country of Origin Labeling (COOL); This Guide Will Tell You What Is COOL & What Is Not 1 (2008), *available at* http://www.consumersunion.org/pdf/CU-Cool-Tool.pdf.

9. Mandatory COOL, 74 Fed. Reg. 2682 (Jan. 15, 2009) (to be codified at 7 C.F.R. pts.60 and 65). The term "retailer" adopted in the final rule is the same definition found in the original Perishable Agricultural Commodities Act of 1930 (PACA) 7 U.S.C. §499(a)(4). Also, this definition, which originally was signified as "dealer", was updated in the 1995 Amendments to the PACA. In addition, the term retailer specifically means any person who purchases more than $230,000 per year of "perishable agricultural commodities". 7 U.S.C. 499(a)(b)(b). Perishable agricultural commodities is defined as "fresh fruits and fresh vegetables of any kind or character). *See* 7 U.S.C. 499a(b)(4), (11).

10. *Id.*

These results, while puzzling to the average person, are nothing new in the United States government's regulation of food.[11]

II. HISTORY

While the COOL provision in its current form was first passed in the 2002 farm bill, some primitive forms of origin labeling requirements have been on the books since the Tariff Act of 1930.[12] The 1930 Act required every imported item to be conspicuously and indelibly marked in English to indicate its country of origin to the ultimate purchaser.[13] This meant that articles arriving at the U.S. border in retail-ready packaging must display the origin identification.[14] But, the 1930 provision exempts articles destined for U.S. processors which are slated to undergo substantial transformation.[15] Also exempted were products on the "J List".[16] While this list exempted such individual items from the labeling requirements, it did require their immediate containers to have country-of-origin labels.[17]

While several other acts throughout the subsequent years modified some substance and form of the labeling requirements, the next major step came with the passage of the 2002 farm bill.[18] This Act required retail-level COOL for fresh produce, red meats, peanuts, and seafood.[19] This Act also exempted further processed foods and restaurant and food service establishments.[20]

The COOL provisions were originally slated to take effect on September 30, 2004, but political wrangling delayed the program starting date twice. The first delay of full implementation occurred

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11. *See generally* Note, *Reforming the Food Safety System: What if Consolidation Isn't Enough*, 120 HARV. L. REV. 1356-57 (2007).

12. Becker, *supra* note 5, at 1.

13. *Id.*

14. *Id.*

15. Becker, *supra* note 5, at 1.

16. *Id* The "J-list" is named because it is found in §1304(a)(3)(J) of the Tariff Act. Becker, *supra* note 5, at 1. The list is specifically created by the empowerment of the Secretary of the Treasury and allows him to specifically exempt certain classes of items. *Id.* The Secretary placed specific agricultural products on the J-list including: natural products such as vegetables, fruits, nuts, berries, and live or dead animals, fish and birds. *Id; see also*, 19 C.F.R. 134.33(2009).

17. 19 C.F.R. 134.33

18. Ron Hale, A COOL Review - Country of Origin Labeling 2003, *available at* www.asi.k-state.edu/desktopModules/ueudocument.aspx?DocumentID=1601.

19. Becker *supra* note 5, at 1.

20. *Id.*

with the passage of The Consolidated Appropriations Act of 2004.[21] The only provision that received a final rule implementing COOL provisions regarded seafood and fish.[22] The seafood and fish provision was championed by the Alaskan Congressional delegation on behalf of the Alaskan fishing industry.[23] Alaskan Senator Ted Stevens was credited with pushing the measure through as a way to support his state's wild fish industry.[24] Another delay on the remaining COOL provisions was passed as part of the 2006 appropriations bill. That provision moved the mandatory implementation date to September, 30 2008.[25]

Many people did not want to see mandatory COOL legislation implemented. Industry trade groups are mostly responsible for the delays in the implementation of COOL. Large producers and qualified grocers lobbied to keep the provision inactive due to their perceived cost increases.[26] Others predicted that the USDA used faulty assumptions and incorrect data in their original calculations of the economic impact on producers, processors, and retailers.[27] Other critics focused on the lack of evidence to support the proposition that COOL labeling will provide valuable information to the consumer or that COOL will lead to an increased demand for covered commodities bearing the U.S. origin label.[28] However, once the Republicans lost control of Congress following the 2006 elections, the way was paved for the final implementation of the COOL provisions.[29]

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21. Consolidated Appropriations Act '04 Pub. L. No. 108-199 at § 749, 118 Stat. 37 (2004).

22. Mandatory Country of Origin Labeling for Fish and Shellfish, 69 Fed. Reg. 59708 (Oct. 5, 2004) (to be codified at 7 C.F.R. pt. 60).

23. Jane Kay, *Seafood to Get Country of Origin Labels,* SAN FRANSISCO CHRONICLE, Feb. 4, 2004, *available at* http://www.organicconsumers.org/foodsafety/seafood020504.cfm.

24. *Id.*

25. Becker, *supra* note 5, at 3.

26. *See* Barry Krissoff, et al., Country-of-Origin Labeling: Theory and Observation, *available at* http://www.ers.usda.gov/publications/WRS04/jan04/wrs0402/wrs0402.pdf.

27. Becker, *supra* note 5, at 5.

28. Letter from John D. Graham, Ph.D. to Hon. William T. Hawks, Under Secretary for marketing and Regulatory Programs, United States Department of Agriculture (Oct. 27, 2003) (on file with the author).

29. Andrew Martin, Labels Lack Food; Origin Despite Law, NEW YORK TIMES, July 2, 2007, *available at* http://www.nytimes.com/2007/07/02/business/02label.html.

ISSUES REGARDING MANDATORY COUNTRY-OF-ORIGIN LABELING

A. Violation of the World Trade Organization's ban on Non-Tariff Barrier's to Trade

1. Brief History of WTO, the Agreement on Agricultural, and NTBs

The World Trade Organization (WTO) is the international forum used by member governments to resolve disputes regarding commerce and trade.[30] While the WTO was officially formed on January 1, 1995, its origins can be traced back to earlier agreements, specifically, the General Agreement on Tariffs and Trade (GATT).[31] The GATT operated from 1947 through the end of 1994 when the WTO assumed and expanded the original GATT.[32] The agreement, known as the Marrakech Agreement after the Moroccan city in which it was signed, created new policy initiatives that expanded the role of the new WTO beyond its original inclusions to reflect new business practices as well as the expansion of the trade of services between member nations.[33]

Prior to 1995, the GATT rules were largely ineffective in regulating the world agricultural trade.[34] Countries created trade imbalance by placing fiscal restraints on imports while simultaneously granting export and domestic subsidies for their own producers.[35] In addition to the subsidy policies, non-tariff barriers (NTBs) were used to stifle market entry.[36] These NTBs included import quotas, regulatory labeling measures, and country of origin requirements.[37] The Uruguay Round of negotiations largely put an end to these disparate policies by enacting the Agreement on Agriculture.[38] The

30. World Trade Organization, http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm (last visited February 9, 2009).

31. *Id.*

32. BERNARD M. HOEKMAN & PETROS C. MAVROIDIS, THE WORLD TRADE ORGANIZATION, LAW, ECONOMICS, AND POLITICS 8 (2007).

33. *Id.* at 11.

34. World Trade Organization, 70 Agriculuture Negotiations: The Issues, and where we are now, at 5, *available at* http://www.wto.org/english/tratop_e/agric_e/agnegs_bkgrnd_e.pdf.

35. *Id.*

36. *Id.*

37. *Id.*

38. World Trade Organization, Agriculture: Fairer Markets for Farmers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm3_e.htm (last visited Feb. 9, 2009).

stated goal of the Agreement on Agriculture was to "reform trade in the sector and to make policies more market-oriented."[39]

The Marrakech Round specifically addressed rules of origin and the WTO regulations that would govern these rules.[40] These rules outlined procedures for implementation, guidelines for requirements, and information for resolving certain disputes within these guidelines.[41]

2. Basis of Claim for Complaining Member-Countries

While no real challenge has been made regarding labeling requirements on agricultural products, a legitimate case can be formed to challenge the new Mandatory COOL legislation recently implemented by the USDA. The history of WTO Rules of Origin resolutions has been limited to a claim between India and the United States regarding apparel and textile labeling rules.[42] Here, the WTO panel upheld the origin labeling laws passed by the United States.[43] This challenge represents the only instance where the WTO has issued a ruling based on the Agreement on Rules of Origin (Agreement).[44] However, the specific language in the Agreement opens the door to challenges for the new U.S. Mandatory COOL legislation. In Article 9 of the Agreement, the WTO describes the trade rules regarding new origin requirements.[45] Article Two (c) specifically states that origin rules should "not themselves create restrictive, distorting or disruptive effects on international trade."[46]

B. Background on Importing Standards and Processing Procedures

When an animal is imported into the United States for processing, the Federal Meat Inspection Act of 1906 (FMIA) says that no

39. *Id.*

40. World Trade Organization, *Agreement on Rules of Origin,* Dec. 2005, *available at* http://www.wto.org/english/docs_e/legal_e/22-roo.pdf.

41. *Id.*

42. *See* World Trade Organization, *Dispute Settlement:* Dispute D5243: United States- Rules of Origin for Textiles and Appeal Products, June 20, 2003 http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds243_e.htm (last visited Feb. 9, 2009).

43. *Id.*

44. U.S. Wins WTO Ruling on India Challenge to textile Rules Washington File, June 20, 2003, *available at* http://news.corporate.findlaw.com/wash/s/20030620/2003062003clt.html.

45. World Trade Organization, *supra* note 41.

46. *Id.*

animal shall be imported "unless they comply with all the inspection, building, construction standards, and all other provisions of this act and regulations issued thereunder applicable to such articles in commerce within the United States."[47] So, an animal imported into the U.S. must comply with all of the safety, inspection, sanitary, and verification standards to which a domestically produced animal must comply.[48] This means that at any given U.S. processing facility, cattle imported from Mexico or Canada must be produced using the same standards as domestically grown cattle. However, under the Mandatory COOL legislation, in order for the domestically grown beef to get the desired "Product of the U.S.A." label, these virtually identical cattle must be segregated during the entire fattening, feeding, and production process.[49] This will add additional segregation costs for the processors at the finishing plants.[50] Additionally, foreign animals are required to have more documentation to evidence their journey through the supply chain.[51] To compensate for the additional costs and remove the chance for mistakes in the segregation process, some U.S. producers are refusing to accept cattle imports.[52]

Another factor affecting processors is the simple economical mechanics of the processing plant. A typical commercial processing plant will process orders for a variety of customers each day. Some will be institutional customers ordering products that, under the interim final rule, are exempt from the COOL requirements because of the restaurant exception.[53] Others will be classic retailers which, under the PACA and the final rule, will require the COOL labeling. This alternating order-filling can create additional difficulty for recordkeeping as well as increase the chances of a segregation error and further increase the costs. In addition, it is estimated that 45% of U.S. beef is processed for sale to customers who either are exempted from COOL under an exception like the restaurant

47. 21 U.S.C. § 620(a).

48. *Id.*

49. Telephone Interview with Mark Dopp, Senior Vice President and General Counsel, The American Meat Institute, in Washington, D.C. (Nov. 13, 2008).

50. *Id.*

51. Iowa Public Television, *Mexico joins Canada in WTO beef dispute vs. U.S.*, Dec. 19, 2008, http://www.iptv.org/mtom/story.cfm/news/1353 (last visited Feb. 26 2010).

52. *Id.*

53. Producers Marketing Association, *supra* note 8.

exception or who further process the beef so that it is exempted from the COOL requirements.[54]

C. Analysis

WTO member-countries that import agricultural products already act within a scheduled framework of certain import controls as well as other methods of regulating imports, such as tariffs.[55] But, in the administration of label of origin rules, member-countries must do so in a manner proscribed in the Agreement.[56] The ultimate goal is to create a system that is easily administered, easily understood, and applied objectively.[57] And as with the WTO in general, the ultimate goal is the free flowing of trade and commerce between member-countries.[58]

With the implementation of the Mandatory COOL, member-countries have a regulatory framework in place to challenge the provisions by virtue of being placed in an economic disadvantage. First, costs will increase due to increased recordkeeping requirements, segregation costs, and product labeling requirements. While cost estimates vary widely within the industry, the USDA estimates that the first year incremental costs for directly affected firms will be around $2.5 billion.[59] Consequently, the report further indicates that the directly affected industries will recover a percentage of their higher costs by raising the price of their products.[60] However, standard economic theory suggests that higher prices will reduce demand for the affected products.[61] In other words, when consumers pay more for the affected commodity, they will purchase less of that

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54. Telephone Interview with Mark Dopp, Senior Vice President and General Counsel, The American Meat Institute, in Washington, D.C. (Nov. 13, 2008).

55. WORLD TRADE ORGANIZATION, NON-TARIFF BARRIERS RED TAPE, ETC., http://www.wto.org/english/theWTO_e/whatis_e/tif_e/agrm9_e.htm (last visited Feb. 9, 2009).

56. *Id.*

57. *Id.*

58. HOEKMAN & MAVROIDIS, *supra* note 33, at 1.

59. Mandatory Country of Origin Labeling, 73 Fed. Reg. p. 45106, 45128 (Aug. 1, 2008) (to be codified at 7 C.F.R.pt. 65) (compare that with the estimates from the VanSickle article which estimate the costs to be somewhere in the neighborhood of $193 million, or 7.7% of the USDA estimate). *But see* VAN SICKLE, ET AL., COUNTRY OF ORIGIN LABELING: A LEGAL AND ECONOMIC ANALYSIS 18 (2003), *available at* http://edis.ifas.ufl.edu/pdffiles/FE/FE38400.pdf (estimating the costs to be somewhere in the neighborhood of 193 million, or 7.7% of the USDA estimate).

60. Mandatory Cool, 73 Fed. Reg. at 45129 (Aug. 1, 2008).

61. *Id.*

commodity and look to replace that commodity with an alternative selection that will provide a better value.[62] For example, if the incremental price of beef increases, consumers might look to replace some beef with chicken in their diet. The chicken industry, unlike the beef industry, is highly vertically integrated, drastically reducing some of the recordkeeping and administrative costs that are predicted to plague the mandatory COOL.[63] Also, pork is less affected by the change in rules since pork, unlike beef and chicken, has a relatively high rate of further processing, which exempts those products from the COOL requirements.[64] The reduced demand for the affected commodities will ultimately reduce the demand for those imported commodities as well, ultimately disadvantaging the importing trade partner.

Additionally, reduced demand and increased hassle on the part of the American producers will likely cause producers to reduce their acceptance of imported affected commodities.[65] The final rule estimates a reduction in the import of beef, pork, veal, and broiler chickens.[66]

Therefore, these reasonable assessments lay the foundation for WTO member-countries to make a prima facie case against the implementation of the Mandatory COOL provisions of this interim final rule. In fact, at the time of this writing, Mexico and Canada have both filed separate complaints with the WTO against the Mandatory COOL legislation.[67]

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62. *Id.*

63. *Id.* at 45130. (This section indicates that 95% of chickens are produced/processed under vertical integration). This means that the integrators, like Tyson Foods for example, own the birds from the time they hatch until the time they sell the birds directly to the retailer. *Id.* This drastically reduces costs associated with record keeping as well as the need for segregation. *Id.*

64. *Id.* at 45131.

65. Klapper, *supra* note 52.

66. Mandatory COOL, 73 Fed. Reg. 45, 129 (Aug. 1, 2008).

67. Klapper, *supra* note 52. *See also* Anna Bahney, Meat Labeling Law Blasted, Feb. 8, 2010, *available at* http://www.argusleader.com/article/20100130/NEWS/1300303/1001/news (discussing that after two failed rounds of negotiation between Canada and the United States, Canada has successfully petitioned the WTO for a panel). This panel represents the next step in the process under current WTO regulations.

III. LACK OF ECONOMIC AND CONSUMER PURCHASING DATA TO SUPPORT A COST/BENEFIT RATIONALE FOR COOL

A. Economic Rationale of Labeling

The food we consume today contains many different ingredients that are grown, processed, or produced in many different places. Producers, governments, retailers, and consumers all play a role in determining which of the various bits of information are actually displayed on food labels.[68] These different contributors often act with very different goals in mind. Consumers desire many different kinds of information including the ingredients contained in a given product,[69] the origin of those ingredients, and even the method of cultivation and harvesting.[70] And the consumer can use their own purchasing power to influence the way companies label their products.[71]

The government's rationale for certain labeling requirements can have different social and economic goals.[72] For example, the government requires many different foods to contain nutritional information.[73] This label may provide the consumer with more information while also furthering the government's social goal of creating a healthier population.[74] By promoting a healthier society, the government aims to enrich the lives of its citizens, as well as reduce costs for government-sponsored healthcare programs like Medicaid and Medicare.[75]

Third parties also have incentives to label their products by highlighting attributes designed to reach certain consumer segments. Products labeled with certain specific information can create a demand for the product among the targeted consumer groups. A popular example of this trend is the rise in "organic" labeled prod-

68. ELISE GOLAN, ET. AL., ECONOMICS OF FOOD LABELING 1 (2000), *available at* http://www.ers.usda.gov/publications/aer793/aer793a.pdf.

69. *Id.*

70. Many consumers are concerned about the use of pesticides, herbicides, harvesting techniques (hand-picked versus machine harvesting, for example), and transportation issues. *See id.*

71. *Id.*

72. *Id.*

73. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LAEBLING GUIDE (1998) *available at* http://www.cfsan.fda.gov/~dms/2lg-7a.html (discussing regulartory requirements under Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act); *21 U.S.C. §301, et. seq., 15 U.S.C. § 1451, et. seq.*

74. Golan, *supra* note 69, at 1.

75. *Id.* at 13-14.

ucts. The National Organic Program, implemented in the early 1990's,[76] was born from the increased demand for certain products grown without chemicals.[77] Producers began to see opportunities to grow this segment of the market to capitalize on the increased demand for these products. Producers also noticed that the increased demand for certified organic foods translated directly into a price premium.[78]

Whatever the underlying rationale, food labeling requirements are being advanced by many different segments of the food supply and regulatory chain. But, as with all costly inputs, economics plays a large role in the decision to label certain products. If the cost to change a label cannot be recuperated with an increase in price or increase in volume, companies do not have an economic incentive to change their label.

B. History of Voluntary COOL Labeling

In October of 2002, the Agricultural Marketing Service (AMS) published the "Guidelines for the Interim Voluntary Country-of-Origin Labeling of Beef, Lamb, Pork, Fish, Perishable Agricultural Commodities, and Peanuts" in the Federal Register.[79] This Voluntary Rule opened the door for producers and retailers to begin labeling their products with country-of-origin information. However, participation in the voluntary program did not garner significant participation.[80] The drafters of the Final Rule noted that this lack of participation primarily indicated consumer's unwillingness to pay

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76. *See generally* 7 U.S.C. § 6501-6522(2000). This comment does not focus specifically on the National Organic Program. For a general overview and history of the National Organic Program and the Organic Food Production Act of 1990, *see* Kate L. Hudson *Organic Plus: Regulating Beyond the Current Organic Standards*, 25 PACE ENVTL. L. REV. 211. (2008).

77. *See* Golan, *supra* note 69, at 26.

78. *Id.*

79. Country of Origin Labeling: Frequently Asked Questions, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5071922 (last visited Feb. 24, 2010). The Agricultural Marketing Service (AMS) is the arm of the USDA charged with the responsibility of drafting and implementing the COOL regulations. The Interim Voluntary Rule was published in the Federal Register at 67 Fed. Reg. 63367.

80. Mandatory COOL, 74 Fed. Reg. 2658, 2682 (Jan. 15, 2009) (to be codified at 7 C.F.R. pts. 60 and 65) (noting, "the lack of widespread participation in voluntary programs for labeling products of United States origin provides evidence that consumers do not have strong enough preferences for products of United States origin to support price premiums sufficient to recoup the costs of labeling").

for country-of-origin information.[81] Some executives in the industry who oppose the mandatory COOL legislation point to this as a signal that Congress passed a bill without empirical data to justify it.[82]

C. Contrasting Participation in the National Organic Program with the Voluntary COOL Program

Food producers continually innovate their labels hoping to ultimately influence consumers to purchase their products versus those of their competitors.[83] While food producers provide a product that is necessary for human existence, most producers' ultimate goal is financial success. And, most producers will seek to market a new or improved attribute if they believe there is money to be made from marketing that desirable attribute of their product to their targeted consumers.[84]

A great example of a consumer-demand driven innovation in voluntary food labeling is the National Organic Program. By the 1980's, the USDA noticed that organically grown produce had formed a distinct market and that "average premiums in the stores ranged from over 40% to as high as 175%."[85] The sale of organic foods exceeded $10.3 billion for 2003, and estimates have set the growth rates over 20% on an annualized basis.[86] From a pure economic standpoint, organic products are more expensive to grow than non-organics.[87] And, in order for organic producers to remain

81. *Id.*

82. R-CALF USA, Separating Fiction from Truth, How the Voluntary COOL Bill will Impact the U.S. Cattle Industry, Sept. 10, 2004, *available at* www.r-calfusa.com/COOL/COOL%20Fact%us%20Fiction.pdf. Boyle stated, "We as consumers want to know pertinent information about the food products we purchase, such as its price, nutritional value, calorie content, sell-by dates and safe handling instructions. But only the Congress, in its infinite wisdom, would believe that consumers are interested in the family tree of fresh meats, produce, seafood and peanuts sold in grocery stores. In fact, surveys repeatedly show that consumers care most about price, freshness and quality." Citing "Make COOL Meat Labeling Voluntary," J. Patrick Boyle, Guest Opinion, Billings Gazette, August 3, 2004.

83. *See* Krissoff, *supra* note 27, at 1-7.

84. *Id.* at 6.

85. Golan, *supra* note 69, at 6.

86. ORGANIC TRADE ASSOCIATION, ORGANIC FOOD FACTS, 1, http://www.ota.com/organic/mt/food.html (last visited Feb. 9, 2009). (The Organic Trade Association is a membership based trade organization who promotes organic initiatives for the organic industry).

87. Golan, *supra* note 86, at 26.

economically viable, they must secure a premium price that covers the additional costs of the organic program.[88]

A sharp contrast to the grass-roots beginning of the National Organic Program is the bureaucratic origin of the COOL legislation. Producers and retailers did not rush to participate in the voluntary COOL program that was implemented in 2002. Several theories have been given to explain why retailers have not found an economic incentive to label their products with the country-of-origin.[89] One idea is that consumers just don't care to know from which country their food originates.[90] The lack of domestic COOL on meat products indicates that most "consumers neither give the product's country of origin much thought nor view imported products as inferior."[91] Another theory says that some consumers prefer certain food items to be imported because they perceive the imported products as being superior to their domestic counterparts.[92] Because certain products are labeled with their exporting country's name prominently displayed on the label, there appears to be an economic benefit to informing the consumer of the product's country-of-origin.[93]

While some studies have indicated that consumers do value COOL information and are willing to pay a premium for this information, even the researchers involved in those studies acknowledge the relative uncertainty of the economic success of a mandatory program.[94] The overall conclusion drawn by most observers is that "the infrequency with which voluntary country-of-origin can be ob-

88. Golan, *supra* note 86, at 26.

89. Krissoff, *supra* note 27, at 6, 7.

90. *Id.* at 6.

91. *Id.* at 7.

92. *Id.*

93. *Id.* (Examples include New Zealand lamb products, Burgundy wine, Parma ham, or Columbian coffee). Krissoff, *supra* note 27, at 7. When consumers associate superior quality with certain regional production and are willing to pay a premium to obtain products from that region, the producer has an incentive to label and advertise the products accordingly. *Id.*

94. Wendy J. Umberger, et. al., *Consumer Demand for Country of Origin and Source Verification Labels, available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3319323; Wendy J. Umberger, et. al., *Country-of-Origin Labeling of Beef Products U.S. Consumers' Perceptions, available at* http://agecon.unl.edu/mark/pdf/Umberger.pdf (Compare Wendy j/ Umberger, et. al's study in March 2003 showing U.S. consumer's willingness to pay on average 19% premium for domestic beef with her co-authored study presented in December 2003 showing that when COOL information was compared with other food attributes such as food safety inspections, tenderness, price and traceability, COOL ranked as the least important attribute to this survey group).

served suggests that food suppliers see little or no advantage in labeling domestic products as domestic."[95] That is to say, consumers are either not willing to pay a premium for the products or the premium derived will not cover the incremental costs of the additional labeling requirements.[96]

IV. CONCLUSION

American consumers like to know the origins of the products they buy. We look at labels on everything from clothes to cars when making a purchasing decision. We associate certain positive qualities with certain country's production of certain products. But, we also stigmatize certain countries with certain products. We also enjoy free trade and the ability to market our products to the world as well as receive products made in every corner of the world.

But our food supply is not like a car or a pair of pants. We pay special attention to the safety and health of the food we eat so that we can remain healthy as well as satisfied. Information about the food we eat comes at a cost to the producers and retailers providing that information. Recordkeeping, testing, verification, and certification costs directly affect the price of everything we buy. While comparing similar products gives us the opportunity to make informed and rational choices, most consumers can neither grasp an infinite list of product attributes nor afford to pay the increased premium for this mountain of information. With the passage and implementation of the Mandatory COOL legislation, Congress has levied an additional "food tax" on the consuming public. Not only could these additional costs create an unfair trade environment for our WTO trading partners, but it could also place some domestic producers in an unfavorable economic position.

Congress should revise the mandatory provision and reinstall the voluntary program as an alternative for people who want to label their products with the country of origin information. Also, this would allow states to regulate their certain food industries where producer and consumer demand for the COOL information can be better recognized and implemented.

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95. Krissoff, *supra* note 27, at 6.
96. *Id.* at 7.

UNITED STATES FOOD LAW UPDATE: INITIAL FOOD SAFETY RESTRUCTURING EFFORTS, POULTRY PRODUCTION CONTRACT REFORMS AND GENETICALLY ENGINEERED RICE LITIGATION

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This edition of the food law update will address recent events that may serve as bellwether signs that significant, long sought changes to the food and agricultural production system may be on the horizon. The first section of the update focuses on several general food safety initiatives. These efforts may, in the near term, coalesce into comprehensive food safety legislation. The second section analyzes two food safety actions relating to specific product categories: oysters and eggs. Section three provides a brief overview of poultry production contracts that may signal a broader restructuring of the legal relationships between farmers and the upstream corporations, which heavily influence production practices. Although none of the events alone create drastic change, combined they reveal a political atmosphere primed for larger restructuring of the food system. Finally, section four discusses two significant jury verdicts in the on-going genetically engineered rice litigation that imposes liability on the developer of genetically engineered seed that became commingled in the international rice supply chain.

As in previous editions of this update, necessity dictates that not every change is included; rather, the authors limited their analy-

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sis to significant changes within the broader context of food production, distribution, and retail. The intent behind this series of updates is to provide a starting point for scholars, practitioners, food scientists, and policymakers determined to understand the shaping of food law in modern society. Tracing the development of food law through these updates also builds an important historical context for the overall development of the discipline.

I. GENERAL FOOD SAFETY INITIATIVES

A. The President's Food Safety Working Group

In recognition of the growing public concern with food safety,[1] and the Government Accountability Office's (GAO) report listing, for the first time, federal oversight of food safety as a "high risk,"[2] President Obama established the President's Food Safety Working Group (Working Group) in 2009.[3] Chaired by the Secretaries of the Department of Health and Human Services (HHS) and the Department of Agriculture,[4] the stated purpose of the Working Group is to "enhance our food safety systems by fostering coordination throughout the government including enhancing our food safety laws for the 21st century."[5] In the typical aspirational language of many new initiatives, the Working Group seeks to "break down stovepipes, address cross-cutting issues and increase coordination of food safety activities across the U.S. government."[6]

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1. Mary L. Nucci, et. al., *The U.S. Food Import System: Issues, Processes & Proposals*, Food Policy Institute Working Paper No. RR-0208-001, at 28(Mar 2008), *available at* http://www.foodpolicyinstitute.org/docs/pubs/Final_Imports_Report_3-08.pdf (citing a study by the International Food Information Council, *available at* http://www.foodinsight.org/Press-Release/Detail.aspx?topic=Food_Safety_Concerns_Do_Not_Include_Biotechnology).

2. *See* U.S. Gen. Accounting Office, HIGH RISK SERIES: AN UPDATE at 26 (Jan. 2007), *available at* http://www.gao.gov/new.items/d07310.pdf.

3. Weekly Address, The White House, Office of the Press Secretary, President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures, (Mar. 14, 2009) *available at* http://www.whitehouse.gov/the_press_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F/(announcing in the weekly address the creation of the Food Safety Working Group).

4. *Id.*

5. *See* Presidents Food Safety Working Group, http://www.foodsafetyworkinggroup.gov/Home.htm (last visited Apr. 15, 2010).

6. *See* FOOD SAFETY WORKING GROUP KEY FINDINGS, at 5, *available at* http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf.

As of this writing, the Working Group has announced several initiatives, but, as discussed below, has not been able to coordinate passage of comprehensive food safety reform in Congress. On July 31, 2009, the USDA and HHS issued a joint announcement noting that "prevention and partnership" would guide their respective agency's food safety efforts.[7] At the center of the announcement were new policies by both agencies. USDA, in a change from previous practice, announced its intention to inspect periodically bench trimmings[8] in beef processing for E. coli contamination.[9] HHS concurrently announced the publication of three draft FDA industry guidance documents to minimize contamination in leafy greens, tomatoes and melons.[10]

To actually solve the "stove-pipe" issues identified as one of the core missions of the Working Group, however, it must go beyond merely issuing joint press announcements of individual agency activities. In October 2009, the Working Group announced a tepid first step in this effort—a cooperative effort between FDA and the Fresh Products Branch of USDA to develop new produce safety rules and a joint outreach effort to assess the impact of these rules on the industry, including small and organic farmers.[11] As another example of increased agency coordination, the Working Group scheduled a public meeting in December of 2009 to improve coordination between FDA and USDA's Food Safety Inspection Service (FSIS). The goal of the integrated effort is to "increase the speed and accuracy of traceback investigations and the traceforward" ca-

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7. Press Release, USDA, Agriculture Secretary Vilsack, Health and Human Services Secretary Sebelius Announce new Strategies to Keep America's Food Supply Safe, No. 0359.09 (July 31, 2009) *available at* http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1RD?printable=true&contentidonly=true&contentid=2009/07/0359.xml.

8. Bench trim consists of the pieces leftover from steaks and other cuts of meat that are subsequently used to make ground beef. *Id.*

9. *Id.*

10. *Id.*; *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm; FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance, available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm173902.htm; FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance, available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174171.htm.

11. Press Release, FDA, USDA Joins FDA Efforts on New Food Safety Regulations: Agencies Unite on Outreach to Produce Industry (Oct. 5, 2009), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm185278.htm.

pabilities of industries confronting a foodborne illness outbreak.[12] Finally, at the close of the year, the Customs and Border Protection, upon the recommendation of the Working Group, opened the Commercial Targeting and Analysis Center (CTAC) to enhance the inspection of imported food products.[13] Although the Working Group undoubtedly has increased the cooperative efforts of the various federal agencies with food safety responsibilities, one must defer judgment of the actual effectiveness of this presidential-level initiative until the coordination efforts solidify into operational changes within the food supply chain, including an assessment of the collective government-industry response to a food safety crisis.

The creation of the Working Group leaves unresolved the question of which government entity should take the lead in food safety oversight and establishing policy—or if a lead agency is necessary. The current shared governance system at the federal level includes fifteen separate agencies with complicated jurisdictional authority, as well as fifty states, each with their own statutes, regulations and agencies.[14] Further complicating the federal allocation of responsibility is the agencies' increased reliance on guidance (rather than notice and comment rulemaking) and marketing orders developed by industry, to develop food safety initiatives that attempt to address evolving threats under existing legislative authority.[15] This fragmentation has led to repeated calls for consolidation and reform.[16]

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12. Press Release, FDA, FDA and FSIS Collaborate to Improve Tracing of Unsafe Food Products (Nov. 5, 2009), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm189311.htm.

13. Press Release, FDA, USDA and HHS Continue Food Safety Working Group Efforts; Customs and Border Protection Opens Import Food Safety Center, *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm193668.htm.

14. *See* U.S. GEN. ACCOUNTING OFFICE, FOOD SAFETY: SELECTED COUNTRIES' SYSTEMS CAN OFFER INSIGHTS INTO ENSURING IMPORT SAFETY AND RESPONDING TO FOODBORNE ILLNESS, at 2 (June 2008) *available at* http://www.gao.gov/new.items/d08794.pdf [hereinafter *Food Safety: Selected Countries Systems*].

15. A. Bryan Endres, *United States Food Law Update: Pasteurized Almonds and County of Origin Labeling*, 5 J. FOOD L. & POL'Y 111, 122-24 (2009) (discussing the increased use of marketing orders for food safety considerations).

16. *See, e.g.*, Michael R. Taylor, *Lead or React?: A Game Plan for Modernizing the Food Safety System in the United States*, 59 FOOD & DRUG. L.J. 399, 399 (2004) (noting that the current system requires "serious modernization" as it is "organizationally fragmented, bound by obsolete statutes, and unable to make the best use of its scarce resources to protect the safety and security of the American food supply"); Timothy M. Hammonds, *It is Time to Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427, 427 (2004) (noting that the current "patchwork quilt creates inconsistencies, gaps, overlaps, and duplication of effort that are becoming increas-

Reform, thus far, has proved difficult. In 2005, a GAO report and recommendation to consolidate the nation's food safety system[17] was met with stiff resistance from key agency stakeholders.[18] A follow up report in 2008 noted that the fragmented federal food safety system "has caused inconsistent oversight, ineffective coordination, and inefficient use of resources . . . [that] calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illness, and focus on promoting the safety and integrity of the nation's food supply."[19] Although the House of Representatives passed a far reaching bill, the Food Safety Enhancement Act,[20] the bill has garnered little support in the Senate. Rather, a related bill that does not reallocate food safety authority from USDA, the FDA Food Safety Modernization Act–sponsored by Senate Assistant Majority Leader Durbin, a long time advocate of food safety reform–has a more promising future, but remains in the Senate

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ingly unworkable"); *Food Safety: Selected Countries Systems,, supra* note 14, at 2 (recommending "that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational structures for food safety"); GAO, *Food Safety: Experiences of Seven Countries in Consolidating their Food Safety Systems* (hereinafter GAO, Food Safety: Exp. of 7 Countries), at 24-25 (Feb. 2005), *available at* http://www.gao.gov/new.items/d05212.pdf (noting that the current federal food safety system "could benefit from statutory and organizational reforms"); *but see* Stuart M. Pape et. al., *Food Security Would be Compromised by Combing the Food and Drug Administration and the U.S. Department of Agriculture into a Single food Agency*, 59 Food & Drug L.R. 405, 406 (2004) (arguing that the "massive, time-consuming, and costly merging of two regulatory agencies" would not result in "a substantial benefit from a food security standpoint", especially in the near term). A subsequent GAO study of the experiences of other countries, however, tends to mollify this concern. *See* GAO, Food Safety: Experiences of Seven Countries, *supra* note 16, at 4 (noting that "government officials in each of the seven countries [subject to the review] believe that these consolidation costs have been or will likely be exceeded by the benefits" including "significant qualitative improvements in food safety operations that enhance effectiveness or efficiency").

17. *See* GAO, Food Safety: Experiences of Seven Countries *supra* note 16, at 24-25.

18. *See id.* at 25-26 (referencing agency comments to GAO report and recommendations); *see also, GAO Calls for Single Food Agency; Veneman Opposes Consolidation*, FOOD & DRINK WEEKLY (Oct 15, 2001) *available at* http://www.allbusiness.com/retail-trade/food-beverage-stores/816846-1.html.

19. *See* GAO, Food Safety: Experiences of Seven Countries, *supra* note 14, at 2.

20. The Food Safety Enhancement Act, H.R. 2749 (passed July, 30, 2009).

Health, Education, Labor and Pensions committee–a victim of Congress' singular effort to enact health care reform legislation.[21]

Absent a legislative overhaul, the President's Working Group perhaps offers a "middle ground" or first step towards coordinating food safety at a higher, inter-agency level. On the other hand, an informal "working group" may be more susceptible to the vulgarities of shifting policy initiatives to satisfy a fickle polity and the needs of an ever-shorter news cycle. To that end, real reform may require a formal institution, such as a dedicated agency, with a singular, focused mission of food safety insulated by at least one institution from the political winds that chart policy at the presidential level.

B. FDA Office of Food

One step toward this coordinated policy, at least at the individual agency level, is the FDA's establishment of the Office of Food. On August 18, 2009, FDA Commissioner Margaret Hamburg created the Office of Food to coordinate the agency's three major operating units relating to food: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the foods-related activities of the Office of Regulatory Affairs (ORA).[22] In addition, the Office of Food is expected to coordinate the agency's implementation of recommendations from the President's Food Safety Working Group and any food safety legislation developed by Congress.[23]

The Office of Food's "One Mission, One Program" initiative to unify FDA's foods program has identified ten critical, cross-cutting topics: preventive controls; risk-based decision-making; inspection and compliance strategy; import safety; federal/state integration; incident preparedness and response; science, technology and research integration; information systems; strategic communications; and resource planning.[24] It will be interesting to see whether the USDA adopts a similar approach to unify its various food safety programs and to what extent these intra-agency initiatives and ac-

21. *See* S. 510, FDA Food Safety Modernization Act. A companion House bill, Safe FEAST Act, H.R. 1332 (2009), is, as of this writing, in both the House Energy and Commerce and Agriculture committees.

22. *See* FDA, *Office of Foods: Overview and Mission*, http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm196720.htm (last visited Apr. 15, 2010).

23. *See id.*

24. *See id.*

companying priority development processes inform the work of the President's Food Safety Working Group.

C. Reportable Food Registry

In addition to the organizational and structural changes discussed in the preceding two subsections–the President's Food Safety Working Group and the FDA's Office of Food–the FDA implemented a significant new food safety initiative to facilitate the tracking of foodborne illnesses–the Reportable Food Registry.[25] Section 1005 of the Food and Drug Administration Amendments Act of 2007[26] required the agency to create a registry for firms to report food safety problems, thereby facilitating the agency's ability to track patterns of adulteration and better target inspections.[27]

Facilities that manufacture, process, pack or hold food,[28] must submit a report through the FDA's electronic portal at http://rfr.fda.gov[29] as soon as practicable after discovery, but within at least twenty-four hours,[30] of a food item "for which there is a reasonable probability that . . . [it] will cause serious adverse health consequences or death to humans or animals."[31] In addition to reporting the adulterated food, the Act requires the reporting party to investigate the cause of the adulteration.[32]

Although these requirements include animal feed and pet food,[33] they do not extend to products regulated exclusively by the USDA under the Federal Meat Inspection Act, the Poultry Products

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25. *See* Department of Health & Human Services, Food and Drug Administration, Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007; Availability, 74 Fed. Reg. 46434 (Sept. 9, 2009); *see also* FDA, Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007, *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm165626.htm.

26. Pub. L. 110-085, codified at 21 U.S.C. § 350f.

27. FDA, Reportable Food Registry [RFR]: At a Glance, at http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM181885.pdf.

28. 21 U.S.C. § 350f(a)(1) (defining responsible parties).

29. FDA, *Guidance for Industry: Questions and Answers*, *supra* note 25.

30. 21 U.S.C. § 350f(d)(1)(A).

31. 21 U.S.C. § 350f(a) (defining "reportable food").

32. 21 U.S.C. § 350f(d)(1)(B).

33. FDA, *Guidance for Industry: Questions and Answers*, *supra* note 25 (answering question number 18, "Are animal feed and pet food included in the definition of reportable food?").

Inspection Act or the Egg Products Inspection Act.[34] This is a significant gap in coverage, as the Center for Disease Control and Prevention (CDC) notes that "[r]aw foods of animal origin are the most likely to be contaminated; that is, raw meat and poultry, raw eggs, unpasteurized milk, and raw shellfish."[35] Moreover, foods derived from or processed with many individual animals to form a batch (e.g., pooled raw eggs, ground beef, broiler chickens) "are particularly hazardous because a pathogen present in any one of the animals many contaminate the whole batch."[36]

Although an important development toward increasing the traceability of foodborne illnesses within the food supply chain, the Reportable Food Registry obviously is not a comprehensive system as it fails to account for most meat and poultry and many egg products. It also highlights the fragmented nature of federal food safety oversight and lends support to those calling for the creation of a single food safety agency that would eliminate the jurisdictional gaps illustrated above. On the other hand, the President's Food Safety Working Group, in accordance with its stated goal of breaking down "stovepipes" and increasing "coordination of food safety activities across the U.S. government"[37] could use this registry as a tool to bridge the divide between the USDA and FDA.[38]

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34. *Id.* (answering question number 22, "Are products regulated exclusively by the USDA subject to the reportable food registry requirements?").

35. Center for Disease Control and Prevention, *Foodborne Illness: Frequently Asked Questions*, at 9 http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#riskiestfoods (answering the question "What foods are most associated with foodborne illness?").

36. Center for Disease Control and Prevention, *Foodborne Illness: Frequently Asked Questions*, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#riskiestfoods (answering the question "What foods are most associated with foodborne illness?"). The CDC notes that "[a] single hamburger may contain meat from hundreds of animals. A single restaurant omelet may contain eggs from hundreds of chickens. . . . A broiler chicken carcass can be exposed to the drippings and juices of many thousands of other birds that went through the same cold water tank after slaughter." *Id.*

37. *See Food Safety Working Group Key Findings*, *supra* note 6, at 5.

38. To that end, the USDA and FDA have developed a "widget" that tracks all food safety information from the respective agencies. *See* http://www.foodsafety.gov/widgets/index.html. This, however, is a long way from the Reportable Food Registry as USDA does not require meat, poultry or egg processors to submit the information upon detection of a food safety issue.

II. SPECIFIC FOOD SAFETY INITIATIVES

In addition to the general attempts to revise the food safety system to be more effective, the Food and Drug Administration (FDA) initiated two specific food safety actions in the fall of 2009. One, a plan to mandate post-harvest processing of Gulf coast raw oysters harvested during summer months, ultimately led to no actual policy change. However, it was politically highly controversial and raises important issues concerning FDA's authority and activities. The other initiative, final implementation of FDA regulations for the control of *Salmonella Enteritidis* in shell eggs, although necessary and reasonable, adds yet another level of complexity to the multi-agency regulation of eggs. Both actions are emblematic of some of the problems in the food safety system that stem from overlapping agency authority, increased use of guidance rather than rulemaking, and inadequate scientific and economic foundations for regulatory decisions.

A. Raw Oysters

In mid October of 2009, the FDA announced a plan to reformulate policies concerning raw oysters.[39] The proposal was to revise the Seafood Hazard Analysis and Critical Control Point standards (HACCP)[40] to require oysters harvested from the Gulf of Mexico during warm summer months to undergo post-harvest processing to reduce the presence of the bacteria *Vibrio vulnificus*.[41] After substantial public uproar in the Gulf coast states,[42] the FDA scaled back its proposal. The agency decided to conduct an "independent study to assess how post-harvest processing or other equivalent controls can

39. *See* Letter from Donald W. Kraemer, Deputy Director, Office for Food Safety, U.S. Food and Drug Administration, to the Interstate Shellfish Sanitation Conference, Oct. 16, 2009, *available at* http://www.fda.gov/NewsEvents/Speeches/ucm187015.htm, *see also* Michael Taylor, Senior Advisor to the Commissioner, Food and Drug Administration, address at the Interstate Shellfish Sanitation Conference Biennial Meeting (Oct. 17, 2009) *available at* http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm.

40. 21 C.F.R. Parts 123 and 1240.

41. *See* Kraemer, *supra* note 39; *see also* Taylor, *supra* note 39.

42. See e.g. Roger Bull, *Florida Oyster Advocates Fuming Over FDA Treatment*, THE FLORIDA TIMES UNION, Nov. 8, 2009, *available at* http://jacksonville.com/business/2009-11-08/story/florida_oyster_advocates_fuming_over_fda_treatment_0; Kris Kirkham, *Louisiana Blasts New FDA Requiring Oysters to be Sterilized to Prevent Rare Bacterial Illness*, THE TIMES-PICAYUNE, Oct. 28, 2009, *available at*_http://www.nola.com/dining/index.ssf/2009/10/louisiana_blasts_fda_plan_to_l.html.

be feasibly implemented in the Gulf Coast in the fastest, safest and most economical way."[43]

1. Background

Vibrio Vulnificus (V. Vulnificus) is a bacterium that occurs in coastal and estuary waters, particularly in temperate zones.[44] Although it is capable of causing infection through open wounds exposed to contaminated water, it is most commonly associated with infections from consuming raw oysters.[45] In healthy individuals it may cause mild diarrhea and stomach cramps, known as gastroenteritis, and there have been no reported fatalities from the gastroenteritis.[46] However, it is a bacterium of major concern to the FDA because it also causes septicemia.[47] These infections occur primarily in individuals with underlying diseases, such as liver disease or diabetes, and almost exclusively after eating raw oysters.[48] With a fifty to sixty percent fatality rate, this makes *V. Vulnificus* the most deadly seafood-borne pathogen, responsible for ninety-five percent of seafood deaths in the United States.[49] When it is not fatal, individuals may develop secondary lesions in which the tissue and muscles develop necrosis and must be amputated.[50] Despite these percentages, *V. Vulnificus* is responsible for relatively few illnesses and deaths compared to other common pathogens in the foods system. The FDA estimates that an average of fifteen people die per year from *V. Vulnificus* infections.[51] Yet as a whole, food borne diseases are esti-

43. Press Release, Food and Drug Administration, Statement on Vibrio Vulnificus in Raw Oysters (Nov. 13 2009) *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnuncements/2009/ucm190513.htm.

44. James D. Oliver, *Vibrio Vulnificus, in* OCEANS AND HEALTH: PATHOGENS IN THE MARINE ENVIRONMENT, 253 (Shimson Belkin and Rita R. Colwell eds., Springer, NY, 2005).

45. *Id.*

46. *Id.* at 257.

47. *Id.*

48. *Id.* at 257-258 (citing W.G. Hlady, *Vibrio Infections Associated with Raw Oyster Consumption in Florida, 1981-1994,* 60 J. FOOD PROT. 1176-1183 (1997)).

49. OLIVER, *supra* note 44, at 258.

50. *Id.* at 259.

51. Food and Drug Administration, Backgrounder on Measures to Eliminate Risk Caused by *Vibrio Vulnificus* Infection from Consumption of Raw Mulluscan Shellfish (Oct. 17, 2009), *available at* http://www.fda.gov/NewsEvents/Speeches/ucm187014.htm.

mated to cause "seventy-six million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States every year."[52]

2. Initial Efforts to Control *V. Vulnificus*

Prior to 2009, the FDA and states made various attempts at reducing infections by *V. Vulnificus*. Most notably, the FDA regulates oysters, as well as all other seafood, by mandating processors implement Hazard Analysis and Critical Control Point (HACCP) procedures. The HACCP regulation requires each processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur."[53] Furthermore, "food safety hazards can be introduced both within and outside the processing plant environment, *including food safety hazards that can occur before*, during, and after harvest."[54] Potential hazards include, but are not limited to, natural toxins, microbiological contamination, chemical contamination, pesticides, and drug residues.[55] If a hazard analysis reveals that a food safety hazard is reasonably likely to occur, the processor must develop a written plan that identifies the hazards that are likely to occur and the critical control points for those hazards, as well as critical limits and testing procedures and frequency provisions for ensuring the critical limits are not exceeded at the critical control points.[56] Processors must take corrective action when deviations from a critical limit occur,[57] and reassess and adjust the HACCP plan on an ongoing basis.[58]

FDA guidance on the implementation of HACCP advises that *V. Vulnificus* is a naturally occurring pathogen (as opposed to pathogens associated with raw sewage and human and animal waste).[59] Currently, control of *V. Vulnificus* requires limiting time from har-

52. Paul S. Mead et. al., *Food-Related Illness and Death in the United States*, 5 EMERG. INFECTIOUS DISEASE 607 (1999), *available at* http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm.

53. 21 C.F.R. § 123.6(a) (2009).

54. *Id.* (emphasis added).

55. 21 C.F.R. § 123.6(c) (2009).

56. 21 C.F.R. § 123.6(b)-(c) (2009).

57. 21 C.F.R. § 123.7(a) (2009).

58. 21 C.F.R. § 123.8 (2009).

59. FOOD AND DRUG ADMINISTRATION, FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS GUIDANCE [hereinafter FDA, FISH AND FISHERIES], Ch. 4 (3d ed. 2001) *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm.

vest to refrigeration.[60] Local Shellfish Control Authorities control for the pathogen by monitoring waters and shutting down harvesting when pathogens are present at dangerous levels.[61] The Shellfish Control Authorities may also impose limits on the time between harvest and refrigeration, depending on the average monthly maximum water temperature.[62] Shellfish intended for raw consumption must bear tags warning of the risk of raw and undercooked consumption.[63] The FDA guide suggests, but does not require, cooking or pasteurization to reduce the pathogens to non-detectable levels.[64]

In addition to these measures, the FDA has conducted outreach and education campaigns to try to reduce the consumption of oysters by at-risk individuals. The FDA developed a Health Education Kit for public health educators to raise awareness of the risk of consuming raw oysters and educate consumers about the safe ways to eat oysters.[65] The FDA also publishes a National Shellfish Sanitation Program Model Ordinance (NSSP) to act as a guide for state regulators to implement safe harvesting, processing and shipping measures.[66] The Interstate Shellfish Sanitation Conference (ISSC), an organization whose members consist of state shellfish control agents from producing and non-producing states, federal agents, industry representatives, and academics, attempts to facilitate nationally uniform adoption of the NSSP.[67]

In 2001, the ISSC adopted a *V. Vulnificus* risk management plan to reduce the number of *V. Vulnificus* illnesses from raw oysters. The plan required states that had "two or more confirmed shellfish-borne *V. Vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from that state (Source State) to develop and implement a *V. Vulni-*

60. *Id.*
61. *Id.*
62. *Id.*
63. *Id.*
64. FDA, FISH AND FISHERIES, *supra* note 59.
65. FOOD AND DRUG ADMINISTRATION, *V. VULNIFICUS* HEALTH EDUCATION KIT (March, 2004), *available at* http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm085164.htm.
66. *See* FOOD AND DRUG ADMINISTRATION, Guide for the Control of Mulloscon Shellfish (2007), *available at* http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm046353.htm.
67. A non-governmental organization that was "formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community." Their home page is http://www.issc.org/Default.aspx.

ficus management plan."[68] The plan sought to reduce reported illnesses (based on data from California, Florida, Louisiana, and Texas) by forty percent by 2005 and by sixty percent by 2007 and 2008.[69] The plan's broad strategies included improving direct communication with the at-risk community, such as through development of educational materials for public health officials, educating the medical community that treats at-risk individuals through presentations at conferences and similar activities, and developing strategic partnerships to broaden message delivery, for instance by developing stronger relationships with pharmaceutical companies that provide medicines to at-risk populations.[70]

Despite these varied efforts, most states have not seen a reduction in deaths or illnesses due to *V. Vulnificus* from consumption of raw oysters. However, the one state that has successfully eliminated *V. Vulnificus* infections is California. In 2003, the California Department of Public Health banned the sale of raw Gulf coast oysters during the summer months.[71] Since implementing the ban, California has not had a single confirmed case of *V. Vulnificus*.[72]

3. FDA Proposed Regulations

The *V. Vulnificus* uproar started in mid-October, when FDA proposed requiring all oysters shipped in interstate commerce to undergo post-harvest processing (PHP) treatments to reduce the presence of *V. Vulnificus*.[73] The agency intended to implement the policy changes in the *Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition*, which is currently under development.[74] The proposed post-harvest processing treatments consisted of individual quick freezing (IQF) with frozen storage, high hydrostatic pressure, mild heat, and low dose gamma irradiation.[75] These technologies are available commercially according to the FDA,[76] but im-

68. GULF & SOUTH ATLANTIC FISHERIES FOUNDATION, *VIBRIO VULNIFICUS* ILLNESS REDUCTION STRATEGIES AND IMPLEMENTATION PROGRAM FOR THE AT-RISK OYSTER CONSUMER: A STRATEGIC PLANNING DOCUMENT, 4, *available at* http://www.issc.org/client_resources/strategic%20plan.pdf.

69. *Id.*

70. *Id.* at 5-6.

71. CAL. CODE REGS. tit. 17, § 13675(c)(5) (2010).

72. *See* Taylor, *supra* note 39.

73. *See id*;.Kraemer, *supra* note 39.

74. Kraemer, *supra* note 39.

75. *Id.*

76. *Id.*

plementation cost is unclear. When the FDA issued the proposal, it did not provide data on the technologies' costs or the projected economic impact on sales for various sized producers, or the industry as a whole. Consequently, one of the most common objections to the implementation of the new program was that the costs of the technologies were prohibitive and the rules would put small processors out of business.[77] Other objections focused on taste and the rights of consumers to access foods they want (i.e., raw oysters),[78] and the apparent unfairness of the action targeted against oystermen when other foods are associated with so many more illnesses and deaths.[79]

The controversy came to a head in early November when legislators introduced two bills designed to prohibit FDA from spending money to enforce the PHP standards.[80] Shortly thereafter, FDA retracted its proposal to mandate PHP and substituted a proposal to conduct further studies on implementing the PHP.[81] Congresswoman Rosa DeLauro (D-CT) subsequently requested the Government Accounting Office to conduct an audit of the effectiveness of the ISSC Risk Management plan in reducing deaths from *V. vulnificus*.[82]

4. Implications of the Revised FDA Proposal.

This action is noteworthy for several reasons, some of which raise issues regarding FDA's policy agenda and implementation strategy. The action is part of the overall effort by the Obama administration to improve food safety and raise its importance at the FDA, as described in Section I, above. Among the various food safety actions the administration has taken includes the appointment of long-time food safety advocate Michael Taylor as Deputy Com-

77. *See, e.g.*, Bull, *supra* note 42.

78. *See, e.g.*, Cain Burdeau, *FDA Plans to Prohibit Sales of Raw Oysters from Gulf*, THE HOUSTON CHRONICLE, Oct 28, 2009, *available at* http://www.chron.com/disp/story.mpl/life/food/6689876.html.

79. *See, e.g.*, Lyndsay Layton, *In Raw Oyster Trade, FDA's Proposal is Tough to Swallow*, WASH. POST, Nov. 10, 2009, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2009/11/09/AR2009110903339.html.

80. Gulf Oyster Protection Act of 2009, H.R. 4022, 111th Congress (2009); Gulf Oyster Protection Act of 2009, S. 2735, 111th Congress (2009).

81. Press Release, FDA, *supra* note 43.

82. Press Release, Congresswoman Rosa L. DeLauro, DeLauro Requests GAO Audit on Reducing Illnesses and Death Due to Contaminated Raw Oysters (Nov. 17, 2009) *available at* http://www.delauro.house.gov/text_release.cfm?id=2686.

missioner for Foods.[83] One of Taylor's most well known actions was successfully implementing HACCP controls for meat and poultry production while head of the Food Safety and Inspection Service (FSIS) at the United States Department of Agriculture (USDA).[84] Taylor's appointment, however, has engendered some controversy among local food advocates due to his close ties to Monsanto Co.[85] Critics fear he will institute policies that indirectly harm small business by failing to take into account the unique needs of such entities in favor of adopting a one-size-fits-all (and that one-size is big business) approach.[86]

Taylor's history, and public perceptions of the implications of this appointment, is relevant to the FDA's oyster proposal because the effort parallels Taylor's implementation of HACCP rules for meat and poultry - shortly after his appointment to FSIS, Taylor announced he was going to mandate HACCP, and then proceeded to do so over vehement objections by the meat and poultry industry. These HACCP regulations are accused of being a primary factor in why slaughterhouse ownership is consolidated into a handful of companies, and the reduction in availability of small scale, local slaughterhouses.[87] Similarly, when the PHP was proposed for oysters, many advocates declared it would destroy mom and pop businesses.[88]

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83. *See* Press Release, Food and Drug Administration, Meet Michael R. Taylor, J.D., Deputy Commissioner for Foods (Jan. 22, 2010) *available at* http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm196721.htm. At the time of the oyster events, Michael Taylor was an advisor to the FDA Commissioner. *See* Press Release, Food and Drug Administration, Noted Food Safety Expert Michael R. Taylor Named Advisor to FDA Commissioner (July 7, 2009) *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm170842.htm. See also Marion Nestle, *Michael Taylor Appointed to FDA: A Good Choice!,* THE DAILY GREEN (July 8, 2009) *available at* http://www.thedailygreen.com/healthy-eating/blogs/healthy-food/michael-taylor-fda-50070809.

84. *See* Nestle, *supra* note 83.

85. *See, e.g., id. See also* Tom Phillpott, *Monsanto's Man Taylor Returns to FDA in Food Czar Role,* GRIST, July 8, 2009, http://www.grist.org/article/2009-07-08-monsanto-FDA-taylor/.

86. Tom Philpott, *Monsanto's Man Taylor Returns to FDA in Food-Czar Role,* GRIST, July 8, 2009, *available at* http://www.grist.org/article/2009-07-08-monsanto-FDA-taylor/.

87. Food and Water Watch, Where's the Local Beef: Rebuilding Small Scale Beef Processing Infrastructure (2009), *available at* http://www.foodandwaterwatch.org/food/report/wheres-the-local-beef-2/.

88. *See* Kirkham, *supra* note 42.

The notable difference between the meat and poultry HACCP and the oyster plan is that political opposition forced FDA to retract its oyster plan. Given the political power of the meat industry, why was USDA able to successfully mandate HACCP, yet the FDA fell apart trying to institute a small policy change to a portion of HACCP rules that already apply to shellfish? Assessing and comparing the variables that impacted these two actions is a research question that needs further investigation. The answers from the study could meaningfully contribute to developing legislation that enables FDA to effectively implement food safety programs tailored to the needs of various scales of production.

The proposed oyster rules provide another example of the FDA's increasing use of guidance documents to implement policies, rather than Administrative Procedure Act (APA) rulemaking.[89] Policy implementation via the APA has the advantage of clearly conveying to the public the agency's goals and purposes, as well as the foundations of its decision. This process also facilitates public acceptance by creating a sense of inclusion in the political process.

In this case, however, FDA provided no data on the economic consequences and failed to convince the public and legislators that it had truly pursued alternative courses of action to control the public health risk from oysters. Furthermore, there was a disconnect between FDA's characterization of the industry's capacity to implement PHP technologies and the media's, politician's, and producer's reactions. Without strong data to support it, the FDA lost its political capacity to move forward with its plan. A potential flaw in the FDA's strategy may have been its decision to take action by changing a policy guidance document, rather than by progressing through the informal notice and comment procedure provided by the APA.[90] A notice of proposed rule, supported by data and the agency's reasoning, would have provided the public and impacted stakeholders an opportunity to comment, and the agency a meaningful, non-political avenue through which to respond to comments and justify its action. The FDA, however, missed this chance and instead faced a media debate.

Yet another issue the oyster action raises is in regards to the FDA's jurisdiction, which is generally limited to food shipped in interstate commerce.[91] Although some gulf oysters are shipped in interstate commerce, many are consumed within the state where they

89. 5 U.S.C. § 500 (2009) *et seq.*; *See also supra* note 15 and accompanying text.
90. 5 U.S.C. § 553(b) (1966).
91. 21 U.S.C. § 331 (2010).

are harvested. Therefore, the FDA's action may not have had the significant impact predicted. Without better public information on where sickness and deaths are occurring, and where the oysters were sourced, it is hard to conclude whether the FDA's action was worth the controversy it engendered.

As congress considers new legislation for the FDA, this issue of the FDA's authority, and the process for its exercise, is important. Should the FDA's jurisdiction be expanded to intra-state goods, or should states remain as "testing grounds" for policies? For instance, the current system has allowed states to experiment with variant regulatory regimes that provide access to unpasteurized milk, a product in high demand by some consumers, while generally restricting its availability to the general public.[92]

B. Egg Handling

Another food safety issue addressed in the second half of 2009 is *Salmonella* Enteritidis (SE) in shell eggs. On July 9, 2009 the Food and Drug Administration (FDA) issued a final rule, effective September 8, 2009, requiring "shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation."[93]

The Center for Disease Control (CDC) first recognized SE as a problem in eggs starting in the 1980s, when it established an epidemiological and laboratory association between eggs and SE outbreaks.[94] There are two primary vectors by which eggs become contaminated: if a hen has Salmonella it may enter the egg during formation and excretion (the transovaraian route) and through contact with contaminated materials (trans-shell penetration).[95] There are numerous programs, administered by several agencies, directed at preventing SE infections.[96] However, the FDA and U.S. Department

92. For a summary of state laws on raw milk, *see* WESTON A. PRICE FOUNDATION, SUMMARY OF RAW MILK STATUTES AND ADMINISTRATIVE CODES, *available at* http://www.realmilk.com/milk-laws-1.html.

93. Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,029, 33,030 (July 9, 2009) (to be codified at 21 C.F.R. Part 118).

94. *Id.* at 33,031.

95. *Id.* at 33,032.

96. Among the programs are the continuous inspection of egg processing facilities and mandatory pasteurization of processed egg products, administered by the Food Safety and Inspection Service, 9 C.F.R. Part 590; the Agricultural Marketing

of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) estimate that of the 47 billion eggs consumed as table eggs (as opposed to eggs made into egg products), 2.3 million are SE-Positive.[97] This translates to a risk of about one in 20,000 eggs.

Although the risk on a per-egg basis is relatively low, SE nonetheless causes thousands of illnesses and hundreds of deaths - estimated in 2001 to be 1,203,650 cases and 494 deaths, while 2004 estimates suggested 1,376,514 cases and 427 deaths.[98] People primarily become ill through eating or drinking food contaminated with the bacteria.[99] As indicated by the above statistics, Americans consume enough undercooked eggs that controlling the incidence of infection warrants attention. The FDA characterizes the rulemaking as "the most recent in a series of farm-to-table egg safety efforts begun by FDA and FSIS in the 1990s.., [it] is the first and only Federal rule that addresses the introduction of SE into the egg during production."[100] This "series of farm-to-table egg safety efforts" has been characterized as the poster-child of a splintered, inconsistent and ineffective food safety system that unevenly allocates resources.[101] However, short of Congressional action to harmonize Federal and State food safety programs and evenly allocate monies based on risk, the somewhat ad-hoc yet coordinated attempts of various agencies to address pressing food safety concerns is better than nothing.

The new rule will require persons with 3,000 or more laying hens at a particular farm that do not sell all of their eggs directly to consumers and that produce shell eggs for the table market to implement shell SE prevention measures.[102] The measures include developing a written SE prevention plan that requires procuring pullets that are SE monitored, using a bio-security program limiting visitors and controlling cross contamination between houses, controlling rodents, files and pests, and cleaning poultry houses be-

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Service's oversight and inspections to prevent cracked, dirty, and otherwise unfit eggs from being sold on the shell egg market, 7 C.F.R. Part 57; the Animal and Plant Health Inspection Service's voluntary breeding program to reduce the incidence of SE in laying hens, 9 C.F.R. Part 145 and 147; and the Food and Drug Administration's mandatory food safety labeling warning, 21 § C.F.R. 101.17(h). For a more detailed discussion of the regulatory morass, *see* Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59 FOOD AND DRUG L.J. 441 (2004).

97. Prevention of Salmonella Enteritidis, 74 Fed. Reg. at 33,032.

98. *Id.* at 33,031.

99. *Id.*

100. *Id.* at 33,033.

101. Eskin, *supra* note 96 at 451.

102. Prevention of Salmonella Enteritidis, 74 Fed. Reg., *supra* note 93, at 33,034.

tween flocks if there was a positive SE test.[103] Producers must do environmental testing for SE when laying hens are forty to forty-five weeks old and four to six weeks after molt;[104] if an environmental test is positive for SE the producer must conduct shell egg testing.[105] Producers must maintain a written SE prevention plan as well as records to verify compliance, which they must make available within twenty four hours of receipt of an official agency request.[106] Shell eggs being held or transported must be refrigerated at or below forty-five degrees Fahrenheit ambient temperature within thirty-six hours of laying.[107] This refrigeration requirement applies to shell egg producers as well as individuals transporting or holding shell eggs.[108]

There were approximately 2,000 comments in response to the proposed rulemaking.[109] The comments covered a broad range of approximately sixty issues; therefore this discussion will focus on a few comments that are relevant to this article's over-all discussion of food safety policies. Several comments suggested that there should not be an exemption for producers with flocks of less than 3,000 hens because these small producers have fewer resources and thus are less likely to have adequate SE prevention measures.[110] The argument that smaller facilities are more likely to have inadequate food safety due to limited resources is common, and in some instances may be justified.[111] However, local food advocates often perceive locally produced food to be safer because of the small scale of production that allows for more careful monitoring and stronger personal connections between the end consumer and the producer.[112] There are likely many factors that contribute to a produc-

103. *Id.* (codified at 21 C.F.R. § 118.4).
104. *Id.* (codified at 21 C.F.R. § 118.5).
105. *Id.* (codified at 21 C.F.R. § 118.6).
106. *Id.* (codified at 21 C.F.R. § 118.10).
107. Prevention of Salmonella Enteritidis, 74 Fed. Reg., *supra* note 93, at 33,034 (codified at 21 C.F.R. §8.4(e)).
108. *Id.* (codified at 21 C.F.R. § 118.1(b)).
109. *Id.* at 33,034.
110. *Id.* at 33,036.
111. For instance, a survey of health inspections by the Salt Lake Tribune found that large chain restaurants had fewer critical health code violations than small, Utah based businesses. Kathy Stephenson, *Chain Eateries do Better in Health Inspections*, THE SALT LAKE TRIBUNE, Oct. 5, 2009 *available at* http://www.sltrib.com/news/ci_13472535.
112. RICH PIROG & ANDY LARSON, CONSUMER PERCEPTIONS OF THE SAFETY, HEALTH AND ENVIRONMENTAL IMPACT OF VARIOUS SCALES AND GEOGRAPHIC ORIGIN OF FOOD SUPPLY CHAINS 10 ,24 (Leopold Center for Sustainable Agriculture, Iowa State University, 2007).

ers' safety record, including scale, finances, general food safety culture and speed of production. According to commenters and the FDA, there is a dearth of research on how scale relates to likelihood of SE contamination.[113] Given this lack of information, and the very small portion of the market occupied by producers with fewer than 3,000 hens, FDA felt that imposing the new regulation on the smallest operations would have little measurable impact on the incidence of SE.[114] Although they may be exempt from FDA's (and many Federal) rules, these small producers likely are still subject to regulation at the state and local level.

Other comments similarly focused on appropriateness of regulations due to scale and economic costs. For instance, some commenters objected to a manure removal requirement because complete removal of all manure becomes difficult in the very large scale houses due to the complexity of the technologies used.[115] FDA's response stated "we do not understand why manure removal at a large operation would be impractical. We acknowledge that a large operation has more manure to handle, but FDA has visited large operations that do clean out the manure, and we are unaware of any unique problems for such operations."[116]

FDA's decision to completely exempt the small producers, yet refusal to accommodate the requests of extremely large producers, raises issues of how to manage problems related to different scales. Food safety policies need to be flexible enough to be capable of assessing the source of risks posed by different types and sizes of production methods in order to adequately control the risks while at the same time allowing for competition between varying producers and facilitating consumer access to foods with desired characteristics. The decision to exempt the small producers relates to common concerns of the local foods movement, including producer ability and dedication to safety controls, economics and fairness, and overall impact on food safety versus per-unit risk. These are many of the same issues that were raised in the raw oyster debate. Like with the raw oysters, lack of clear information and scientific standards for decision making may be hampering effective implementation of food safety programs.

The oyster and egg actions raise the question of how to direct FDA to balance competing factors. Should decisions be based on the

113. Prevention of Salmonella Enteritidis, 74 Fed. Reg., *supra* note 93, at 33,036.
114. *Id.*
115. *Id.* at 33,039.
116. *Id.*

risk the food presents, or the risk of the scale of the outbreak, or some other factor, such as the corporate culture and compliance history, as well as the scale of the producer? And should economics play a role in the decision making? Other regulatory regimes, such as the Clean Air Act, require balancing economic costs against public health benefits.[117]

Accommodating competing scales of production while maintaining competitive balance goes to the heart of the new poultry production contract rules discussed below.

III. REVISED POULTRY CONTRACTING RULES

On December 3, 2009, the Grain Inspections, Packers and Stockyards Administration (GIPSA) of the U.S. Department of Agriculture (USDA) amended a regulation under the Packers and Stockyards Act[118] to improve protections for poultry producers entering into poultry production contracts.[119] The changes seek to address some longstanding abuses in the poultry industry.

In general terms, production contracts are agreements whereby companies hire farmers for their growing services,[120] usually to raise crops or animals. The company often provides the raw inputs, such as seeds and chemicals or animals and feed, while the farmer invests in the equipment and provides the labor. Although production contracts are used throughout agriculture, they are remarkably prominent in the poultry sector.[121] In the poultry industry, five firms control eighty percent of production[122] and farmers raised ninety-five percent of poultry under a contract with a processor.[123] In the U.S.

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117. For instance, the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, bars construction of new polluting facilities unless they make use of the "best available control technology." 42 U.S.C. § 7475(a). A "best available control technology" is "an emission limitation based on the maximum degree of reduction of [pollution]... which the permitting authority, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such facility." 42 U.S.C. § 7479(3).

118. 7 U.S.C. §§ 181-229c (2010).

119. Poultry Contracts; Initiation, Performance, and Termination, 74 Fed. Reg. 63271 (Dec. 3, 2009) (to be codified at 9 C.F.R. § 201.100).

120. JAMES M. MACDONALD, ECONOMIC RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE, THE ECONOMIC ORGANIZATION OF U.S. BROILER PRODUCTION 3 (2008).

121. *Id.*

122. RENEE JOHNSON, GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, LIVESTOCK MARKETING AND COMPETITION ISSUES 6 (2009).

123. *Id.* at 7.

broiler industry, processing firms called "integrators"[124] own hatcheries, processing plants, and feed mills. These integrators contract with independent farmers to "grow out" broiler chicks to market weight, and to produce replacement breeder hens for hatcheries.[125]

Under a poultry production contract, a poultry integrator will contract with a poultry grower to raise birds of which the poultry integrator retains ownership. The integrator typically supplies feed, medicine and other inputs, while the poultry grower provides labor and invests in equipment and structures to raise the birds.[126] A 30,000 square foot broiler house can cost $300,000, and most growers have multiple houses.[127] Payment structures generally are on a performance basis relative to other farmers who deliver birds to the integrator within a certain time period.[128] Farmers receive a flat base fee, and those who deliver more meat per chick delivered are paid extra.[129] Consequently, differences in payment are driven by differences in chick mortality and feed efficiency.[130] Chick mortality depends on the health of the chicks delivered, and feed efficiency depends on the quality of the feed delivered. Because the integrators provide the chicks and the feed, these are factors that are beyond the grower's control.

Once growers have entered the poultry production industry, they often have very limited options for selling their birds. Although only a quarter of respondents to USDA-ERS's poultry production survey reported only one integrator in their area, fifty-nine percent of respondents in the 2004 Agricultural Resource Management Survey reported that they had no alternatives in the form of other contractors, case markets or both, to their current contractor.[131] In the final rulemaking, GIPSA recognized that it is "common knowledge" that vertical integration and high concentration allow poultry integrators to present poultry growers with "take it or leave it" con-

124. Under section 182(10) of the Packers and Stockyards Act, integrators are defined as "live poultry dealers." Throughout the article, the authors will use the term integrator but the reader should be aware that the term is synonymous with a dealer as referred to in the act and regulations.

125. JOHNSON, *supra* note 122, at 5.

126. *Id.*

127. MACDONALD, *supra* note 120, at 7.

128. *Id.*at 3.

129. *Id.*

130. *Id.*

131. *Id.*

tracts.[132] Because of the lack of alternatives, "poultry growers do not realistically have the option of negotiating more favorable poultry growing arrangement terms."[133]

The terms of the contracts make poultry production an increasingly difficult profession from which to make a living. There are several practices that present particular hardship for poultry growers. First, poultry growers are often asked to invest large amounts of capital in building infrastructure for raising the birds without first receiving a written contract.[134] Banks make the loans based on letters of intent from the poultry integrator, often requiring the farmer to put up their farmland and home as collateral.[135] The consequence is that farmers must agree to the terms of the contracts the integrator ultimately provides; otherwise, they are at risk of losing their farm and their home.[136] As farmers pay off their debts, the companies will require them to take out further loans to make improvements on the farm as a precondition to contract renewal, which has the effect of keeping the farmer indebted and vulnerable.[137]

Because the farmer lacks leverage, integrators are able to write onerous terms into the contracts. Payment is often on a ranking system that compares growers within a region to each other based on their success at putting weight on the birds during the seven to nine week contract period.[138] The quality of feed and health of the chicks are two of the largest determinants of how quickly chickens will put on weight. Because the companies control the inputs (birds and feed), integrators can use the inputs as a means of retaliating against growers who try to organize or resist the companies' control.[139] If a producer performs particularly poorly, they may be placed on a Performance Improvement Plan (PIP) and ultimately have their growing arrangement terminated.[140] Other potentially abusive terms include mandatory arbitration clauses, which require costly upfront

132. Poultry Contract; Initiation, Performance, and Termination, 74 Fed. Reg. at 63271.

133. *Id.*

134. *Economic Challenges and Opportunities Facing American Agricultural Producers Today, Hearing Before the S. Comm. On Agriculture, Nutrition and Forestry*, 110th Cong. (2007) (statement of Scott Hamilton, poultry grower from Phil Campbell, Alabama).

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. Statement of Scott Hamilton, *supra* note 134.

140. 74 Fed. Reg. *supra* note 94, at 63272.

fees for the grower, and clauses that prohibit the farmers from discussing the terms of the contract with anyone, including family, lawyers, and financial advisors.[141]

The underlying cause of the integrators ability to abuse growers is the vertical integration and consolidation of the industry into the hands of a few companies. Although the Packers and Stockyards Act prohibits unfair practices,[142] GIPSA does not have anti-trust authority, which limits its ability to address the problems of integration and consolidation. GIPSA authority is limited to temporary injunctions,[143] civil fines,[144] and referral to the Department of Justice to enforce antitrust laws.[145] Furthermore, GIPSA investigations into industry practices tend to be poorly executed and generally inadequate.[146] This situation has allowed the poultry integrators to expand their coercive practices with little chance of legal or financial repercussions.

Congress has considered various measures to address these abuses, but few have successfully passed.[147] For instance, there were provisions in the Senate version of the 2008 Farm Bill, specifically Senator Harkin's version, that sought to amend the P&SA to strengthen USDA enforcement over live poultry dealers, prohibit confidentiality clauses, and limit processor's right to terminate contracts where the producer had invested more than $100,000 in capital.[148] The only changes included in the final bill were provisions allowing producers to cancel a contract within three days; [149] requiring contracts to disclose on the first page that additional large capital investments will be required;[150] and provisions intended to give pro-

141. *Id.* at 63271-63272. Some states have passed statutes prohibiting this and many other practices associated with production contracts. *See* 505 ILL. COMP. STAT. 17/30(2009) (prohibiting complete confidentiality in these production contracts); ARK. CODE ANN. §2-32-201 (2009); IOWA CODE §202.3(2009); MINN. STAT. § 17.710 (2009).

142. 7 U.S.C. § 192 (2006).

143. 7 U.S.C. § 228a (2006).

144. 7 U.S.C. § 228b-2(b) (2006).

145. 7 U.S.C. § 224 (2006).

146. *See generally*, USDA, OIG AUDIT REPT. NO. 30601-01-HY, GIPSA'S MANAGEMENT AND OVERSIGHT OF THE PACKERS AND STOCKYARDS PROGRAMS (2006), *available at* http://www.usda.gov/oig/webdocs/30601-01-HY.pdf.

147. *See* JOHNSON, *supra* note 122, at 15-22 (discussing recent congressional actions).

148. *Id.* at 18-21.

149. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 11005, 122 Stat. 1651 (codified at 7 U.S.C. § 197a).

150. *Id.*

ducers more leeway in choice of venue,[151] choice of law, [152] and the use of arbitration clauses.[153] The 2008 Farm Bill also requires USDA to publish regulations within two year to establish criteria in determining:

> (1) whether an undue or unreasonable preference or advantage has occurred in violation of such Act;
>
> (2) whether a live poultry dealer has provided reasonable notice to poultry growers of any suspension of the delivery of birds under a poultry growing arrangement;
>
> (3) when a requirement of additional capital investments over the life of a poultry growing arrangement or swine production contract constitutes a violation of such Act; and
>
> (4) if a live poultry dealer or swine contractor has provided a reasonable period of time for a poultry grower or a swine production contract grower to remedy a breach of contract that could lead to termination of the poultry growing arrangement or swine production contract.[154]

The notice of rulemaking states:

> The failure of a live poultry dealer to deliver a written poultry growing arrangement in a timely manner is considered by GIPSA to be an unfair and deceptive practice because growers could not otherwise know what the poultry growing arrangement terms will be or whether the terms accurately reflect the agreement reached between the parties. This practice could also be considered discriminatory if some growers receive written poultry growing arrangements in a timely fashion and others do not. A live poultry dealer's failure to include written notice of termination procedures in the poultry growing arrangement and failure to provide a written notice of termination is also considered unfair, discriminatory and deceptive for the same reasons.
>
> A live poultry dealer's failure to include information about Performance Improvement Plans (PIPs) is similarly unfair and discriminatory if some growers receive this information and others do not, and deceptive if growers are unaware that such a program exists until they fail to meet a minimum performance threshold that was not specified in their poultry growing arrangement.
>
> GIPSA considers prohibiting growers from discussing poultry growing arrangement terms with business advisers unfair because growers are not typically attorneys or accountants. Depriving growers of professional advice before they commit to a poultry growing arrangement, particu-

151. *Id.* (codified at 7 U.S.C. § 197b).
152. *Id.*
153. *Id.* (codified at 7 U.S.C. § 197c).
154. *Id.* at § 11006.

> larly when the live poultry dealers have access to such advice in drafting their poultry growing arrangements, is considered unfair as well.[155]

The new regulations will require integrators to provide growers with the true written contract on the date they provide the grower with the poultry house construction specifications and prohibit confidentiality clauses that limits growers' right to discuss a poultry growing arrangement offer with a Federal or State agency, financial advisors or lenders, legal advisors, accounting representatives, other growers who contract with the integrator, and members of the growers' immediate family or business associates.[156] The Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill) created a right for farmers to discuss contracts.[157] GIPSA's list largely re-enumerates the list of individuals that the 2002 Farm Bill protected, with the addition of the right to discuss contracts with other growers who have entered into poultry growing arrangements with the same live poultry dealer.[158] GIPSA added this class of individuals because they "see no benefit for a live poultry dealer to forbid its growers from discussing the terms of their poultry growing arrangements with each other. To do so would impede the growers' ability to determine whether they have been treated unfairly or discriminated against in violation of the P&S Act."[159]

The contract must specify whether a PIP exists for that grower, and if so, any PIP guidelines including the factors considered when placing a grower on a PIP, assistance provided while on a PIP, and factors considered when determining whether a grower will be placed back in good standing or have their arrangement terminated.[160] The purpose of this provision is to prevent integrators from adding PIP riders to an existing arrangement; rather, the integrator will have to fully disclose the existence of the program before a grower enters into the arrangement.[161] Given the large financial debt often necessary to initiate the growing arrangements, it is important for growers to fully understand the full range of expectations and outcomes. This changed provision should help farmers understand

155. Poultry Contracts; Initiation, Performance, and Termination, 74 Fed. Reg. at 63,271.

156. *Id.* at 63,277 (codified at 9 C.F.R. § 201.100(a) and (b)).

157. Pub. L. No. 107-171, §10503, 116 Stat. 134 (2002) (codified at 7 U.S.C. § 229b).

158. Poultry Contracts; Initiation, Performance, and Termination, 74 Fed. Reg. at 63,273.

159. *Id.*

160. *Id.* at 63,277 (codified at 9 C.F.R. § 201.100(c)).

161. *Id.* at 63,273.

changes to normal practices that are likely to occur when placed on a PIP, so they can better judge how it will affect them.[162] This up-front information should be valuable for growers considering entering into growing arrangements with large integrators and significantly expanding their poultry operations.

Finally, parties to a growing arrangement must provide ninety days notice of termination of their growing arrangement.[163] Integrators must provide reasons for the termination, effective dates, and any right to appeal.[164] It is important to note that this rule requires written notice for all situations where one party elects to end the poultry growing relationship, whether it be through non-renewal of an arrangement, discontinuance of the current arrangement, offering of new contract terms, and early termination.[165] This broad coverage is important because many arrangements exist on a flock-to-flock basis, which, in the case of chickens, generally last only seven to nine weeks. This prevents integrators from evading the rule by simply only offering flock-to-flock arrangements.

Currently, most growing arrangements provide for three to thirty days written notice of termination prior to picking up the final flock or prior to the anticipated delivery date for the next flock.[166] In the notice of proposed rulemaking, GIPSA proposed a minimum thirty days notice.[167] Many commenters suggested that thirty days was insufficient for poultry growers to make other business arrangements.[168] GIPSA recognized this and the final rule requires ninety days notice.[169] GIPSA suggests this additional time will allow the grower time to "work with the live poultry dealer [integrator] to improve his/her performance, obtain legal and/or financial advice or guidance, obtain a new contract with a new live poultry dealer, and/or sell his/her poultry growing business."[170] Although ninety days may be sufficient to allow these events to occur, the reality is that most growers do not have access to alternative markets, the law

162. *Id.*
163. Poultry Contracts; Initiation, Performance, and Termination, 74 Fed. Reg. at 63,277 (codified at 9 C.F.R. § 201.100(h)).
164. *Id.*
165. *Id.* at 63,274.
166. *Id.*
167. Prevention of Salmonella Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56,824, (Sept. 22, 2004).
168. Poultry Contracts; Inspection, Performance, and Termination, 74 Fed. Reg. at 63,274.
169. *Id.*
170. *Id.*

provides limited recourse to demand reimplementation, and the properties are highly specialized for poultry growing. However, the market's vertical integration and consolidation, regardless of the duration of notice given, imposes serious challenges on the terminated farmers' ability to successfully continue their operations.

Although the changes to the new regulation should provide farmers who have not yet entered the poultry industry with valuable information, it provides little protection for producers who have already acquired significant debt and are dependant on continued contracts with the integrators to pay off those debts. For them, improved information is not going to drastically impact their ability to negotiate a favorable contract. This improves the well informed, arms length negotiations of new contracts, but does not address the fundamental problem of significant disparity in market power and competitive alternatives, and thus bargaining power. The USDA and Department of Justice have started investigations into anti-competitive activities in the agricultural sectors.[171] There may be future actions that seek to address the larger issues of consolidation in the marketplace. However, if government wishes to meaningfully reform power relations in the poultry industry, fundamental changes in the anti-competitive laws and improvement in USDA's capacity to investigate and eliminate unfair practices is a necessary prerequisite.

IV. GENETICALLY MODIFIED RICE LITIGATION

On December 4, 2009, a federal jury in St. Louis, Missouri awarded two farmers approximately $2 million in compensatory damages for their economic losses arising from the commingling of their rice crops with an experimental (unapproved for general cultivation) genetically modified rice variety.[172] This was the first of several test cases brought by farmers and various entities in the international rice supply chain seeking recovery from the economic losses related to the contamination of rice seed stock with Bayer CropScience's (Bayer) LL601 biotech rice variety. In total, over 7,000 rice farmers and others involved in the global rice supply chain have

171. *See* Dept. of Justice Public Workshops: Agriculture and Antitrust Enforcement Issues in Our 21st Century Economy, http://www.justice.gov/atr/public/workshops/ag2010/index.htm (last visited Aug. 03, 2010).

172. *In re Genetically Modified Rice Litig.*, Case No. 06-md-01811 (E.D. Missouri). For a website containing updated court documents from the rice litigation, *see* www.bayerricelitigation.com.

filed suit against Bayer–5,000 in federal court consolidated in the Eastern District of Missouri and 2,000 in various state courts.[173] This section of the update discusses the jury verdict noted above as well as the court's prior ruling on the consolidated summary judgment motions of the parties seeking redress from Bayer in federal court.[174] A brief summary of the facts giving rise to these disputes follows.

In June 2006, Riceland Foods, the nation's largest rice cooperative, informed Bayer that it detected the presence of genetically engineered rice in the 2005 Midwest rice harvest.[175] Bayer confirmed this finding and reported the results to USDA. Although USDA had approved two varieties of genetically engineered rice for commercial release–LLRice06 and LLRice62–Bayer had not sought approval for the LL601 variety.[176] Bayer had elected not to market the approved rice varieties nor to obtain USDA clearance for the LL601 variety because growers had no interest in producing rice not yet approved for consumption in the major export markets of Japan and the European Union. USDA publically announced the rice contamination on August 19, 2006, precipitating an immediate decline in rice futures, the pulling of U.S. rice from European grocery shelves and, not surprisingly, the filing of multiple lawsuits.

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173. *In re Genetically Modified Rice Litig.*, 2010 WL716190, 2 (Feb. 24, 2010, E.D. Mo.).

174. *See, In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004 (E.D. Mo. 2009). Plaintiffs' counsel estimates another 6,000 farmers will have claims in addition to the approximately 1,000 awaiting trial. In addition to the federal lawsuits, in March 2010 an Arkansas state court jury awarded just over $1 million to a farmer, including $500,000 in punitive damages assessed again Bayer. All Business.com, *Bayer ordered to pay farmer $1 million is tab for modified rice*, http://www.allbusiness.com/legal/torts-damages/14079681-1.html (last visited July 19, 2010).

175. There are two primary rice growing regions in the United States–the southern Midwest/Gulf states and California. USDA, Economic Research Service, *Rice: Background*, http://www.ers.usda.gov/Briefing/Rice/background.htm (last visited Apr. 14, 2010). Long-grain rice, the source of the contamination, is grown exclusively in the South. *See id.*; *see also* Nathan Childs, USDA, *Rice Outlook and Yearbook 2006*, at http://usda.mannlib.cornell.edu/usda/ers/RCS-yearbook//2000s/2006/RCS-yearbook-12-20-2006.pdf (last visited June 25, 2010). (noting decline in long-grain exports due to contamination with LL Rice 601); APHIS, Biotechnology Regulatory Services, USDA Provides Update for Farmers on Genetically Engineered Rice (Feb. 2007) (describing USDA's investigation of the long-grain rice contamination), *available at* http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/ia_ge_rice.pdf.

176. A. Bryan Endres & Justin G. Gardner, *Genetically Engineered Rice: A Summary of the LL Rice 601 Incident*, Agric. L. & Tax Brief 06-04 (Dec. 2006); *See* Seedquest, *U.S. Department of Agriculture issues update for rice industry regarding Clearfield 131 long-grain rice seed*, (March 9, 2007), *available at* http://www.seedquest.com/News/releases/2007/march/18661.htm.

The jury verdict, noted above, in favor of two farmer test plaintiffs from Missouri was the first of multiple lawsuits against Bayer. The second bellwether trial of Arkansas and Mississippi farmer plaintiffs commenced in January 2010, and resulted in a similar victory for the plaintiffs of approximately 1.5 million dollars.[177] A third test trial involving a non-farmer plaintiff (Riviana Foods, Inc.) will begin on April 19, 2010. As discussed in more detail below, the contaminated rice litigation draws heavily from the precedent established in the Starlink genetically modified corn commingling events in 1998-2000 growing seasons, which culminated in the landmark *In re Starlink* decision.[178] Although without doubt an important event in the development of case law impacting production agriculture, the ongoing rice litigation may have a greater impact in the development of a common law relating to biotech commingling and trace-back liability in the discipline of food law by providing an anchor point for further litigation and/or regulatory action.

As a starting point for assessing the impact of this regulation, the following section analyzes the court's detailed October 2009 order accompanying its summary judgment ruling.[179]

A. In re Genetically Modified Rice Litigation *Summary Judgment*

Defendants successfully defeated many of the plaintiffs' causes of action on summary judgment.[180] The court, however, allowed claims for negligence and private nuisance from the "negligent contamination of the nationwide rice supply" leading to "market losses and damage to other property, including equipment, land, and rice" to proceed to trial. Of particular importance to the success of plaintiffs' suit was the USDA's current regulatory position on the low

177. *See Verdict Lands Farmers Money*, STUTTGART DAILY LEADER (Feb. 8, 2010), *available at* www.stuttgartdailyleader.com/features/x644563964/Verdict-lands-farmers-money.

178. *In re Starlink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 841-42 (N.D. Ill. 2002). *See also* D. L. Uchtmann, *StarLink-A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 160 (2002) (discussing the history of Starlink commingling and the regulatory responses).

179. *See In re Genetically Modified Rice Litig.*, 666 F. Supp.2d 1004 (E.D. Mo., 2009).

180. *Id.* at 1004-05. Plaintiffs alleged claims of negligence, public and private nuisance, negligence per se and violation of the North Carolina Unfair Trade Practices Act. The court granted summary judgment in favor of Bayer for plaintiffs' claims for negligence per se, public nuisance and violation of the North Carolina Unfair Trade Practices Act. *Id.* at 1004.

level presence (LLP) of regulated (unapproved for general commercial release) genetic events.

The USDA acknowledges that plant breeding may result in the mixing of genes and gene products from unintended plant sources, whether from pollen drift or human-induced commingling.[181] This mixing may result in the unauthorized introduction of genetically modified plant material into seeds and grain.[182] Recognizing this risk, the Animal and Plant Health Inspection Service (APHIS),[183] in 2002, revised its field testing requirements to prevent the unintended transfer of regulated genetically modified material.[184] In the event of an unauthorized release, APHIS will investigate and determine appropriate remedial or enforcement actions, if any, required by the agency or product developer.[185] In 2008, as part of a proposed revision of the agency's biotechnology regulatory program, APHIS announced a change to its LLP response.[186] Specifically, APHIS proposed to establish criteria under which the agency would not take remedial action for LLP that is unlikely to result in the "introduction or dissemination of a plant pest or noxious weed."[187] Although APHIS has not yet finalized this proposed regulatory change, the agency declined to impose remedial action or impose a fine against Bayer in response to the LL601 commingling.[188]

In its motion for summary judgment, Bayer raised the agency's LLP response to the rice contamination (no action against Bayer), as well as the agency's proposed LLP revisions to its regulatory program. The court, however, rejected Bayer's argument that the agency's proposed regulatory revisions and decision to forego regu-

181. *APHIS* Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials, 72 Fed. Reg. 14,649, 14,649 (Mar. 29, 2007)(to be codified at 7 C.F.R. pt. 340).

182. *Id.*

183. APHIS is the USDA sub-agency responsible for regulation of genetically engineered plant material. *See* 7 C.F.R. pt. 340, (2009) (implementing the Plant Protection Act, 7 U.S.C. § 7701-7772 and 7781-7786).

184. Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,578, 50,578 (proposed Aug. 2, 2002).

185. *Id.*

186. Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008, 60,025 (proposed Oct. 9, 2008).

187. *Id.*

188. USDA, BIOTECHNOLOGY: NONCOMPLIANCE HISTORY, *available at* http://www.aphis.usda.gov/biotechnology/compliance_history.shtml (last visited Apr. 13, 2010).

latory action served in essence as a federal permit for low-level presence in the US rice supply.[189] Rather, plaintiffs were correct in stating that the current regulations would not allow LLP.[190] Bayer had a duty to ensure that the GM trait did not "escape and contaminate other non-GM rice" and this was a "known and foreseeable risk" of conducting field trials (because federal law required strict containment, a common law duty arose).[191]

This regulatory breach (i.e., LLP), however, did not support a claim of negligence *per se*, as the performance standards outlined in the regulations did not provide a standard of care.[192] Moreover, the court held that both industry practices and the regulatory scheme are relevant to the standard of care, but the parties cannot rely on compliance or non-compliance with regulations as evidence for or against liability.[193]

With respect to the common law tort claims for negligence and private nuisance, the court denied Bayer's motion for summary judgment based on the economic loss doctrine.[194] The court distinguished two prior cases involving "the negligent spread of GM food" in which farmers who had purchased contaminated seed directly from the seed company could not proceed to trial due to application of the economic loss doctrine. One case arose in the same court (E.D. MO) in which the court granted defendant's motion for summary judgment on a poorly documented nuisance claim involving unapproved-in-EU corn and soybeans.[195] The other case involved Aventis (a predecessor to Bayer) and applied Wisconsin and Illinois law to bar claims from growers who purchased contaminated seed (while allowing claims of those whose corn was commingled via pollen drift or other means to proceed).[196] Although the LL601 plain-

189. *In re Genetically Modified Rice Litig.*, 666 F. Supp.2d at 1121-1122.

190. *Id.* at 1020-21.

191. *Id.* at 1024.

192. *Id.* at 1022. *See also* RESTATEMENT (SECOND) OF TORTS § 288B(2) (1965) (noting that where a statute fails to provide a standard of conduct, the "fact of the violation may still be accepted as relevant evidence bearing upon the conduct of a reasonable man in the actor's position").

193. *In re Genetically Modified Rice Litig.*, 666 F. Supp.2d at 1024.

194. *Id* at 1016-17. The economic loss doctrine bars recovery of monetary loses in tort cases if there is not accompanying personal injury or physical damage to property. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 21(1998).

195. *Sample v. Monsanto Co.*, 283 F. Supp. 2d 1088, 1092-94 (E.D. Mo. 2003).

196. *In re Starlink*, 212 F. Supp. 2d at 841-42. The Starlink corn variety had approval only for feed or fuel use (not food) in the United States. *Id.* at 834. Testing by the environmental group Friends of the Earth revealed commingling with the US food supply and precipitated a massive recall effort by Aventis to direct the con-

tiffs allegedly purchased contaminated seed, they did not buy it from Bayer. Rather their harvested crop was "injured by Bayer's negligent contamination of the nationwide rice supply," which made the economic loss doctrine inapplicable to their claims.[197]

B. Punitive Damages

While no punitive damages were awarded in this initial verdict, Bayer cannot collaterally estop the thousands of other plaintiffs from having their day in court to seek punitive damages.[198] In consolidated cases, each test plaintiff seeking punitive damages requires an "individualized hearing,"[199] presumably to provide the defendant with due process and to give each plaintiff their day in court on the subject of defense misconduct.

Plaintiffs alleged that Bayer (the successor to Aventis CropScience) and its subsidiaries were responsible for both Starlink corn and LL601 rice crop commingling, thereby justifying an award of punitive damages. In denying Bayer's motion for summary judgment on the claim for punitive damages, the court cited disputed issues of Bayer conduct. For example, did Bayer: 1) ascertain whether the LL601 field trials were planted too close to foundation seed, 2) monitor for unauthorized releases of LL601 outside areas in which it was planted, and 3) verify whether the LSU "cooperators" were taking necessary steps, such as cleaning their equipment and boots, properly storing the rice, or adequately documenting compli-

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taminated corn to non-food uses. Organic Consumers Association *Biotech Firm Executive Says Genetically Engineered Corn is here to Stay*, (Mar. 19, 2001), *available at* www.organicconsumers.org/ge/starlinkforever.cfm. Unfortunately, subsequent testing for traces of the contaminated corn continued for at least eight years. EPA White Paper Regarding StarLink Corn Dietary Exposure and Risk, 73 Fed. Reg. 22,715, 22,716 (Apr. 25, 2008).

197. *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d at 1016-17.

198. *See, e.g., In re Vioxx Products Liability Litigation*, MDL 1657 (U.S.D.C E.D. La. Jun. 5, 2007) (awarding punitive damages in "bellwether" test trial to one of thousands of plaintiffs) *available at* http://vioxx.laed.uscourts.gov/Orders/Barnett.o&r.pdf ; *In re Vioxx Products Liability Litigation*, 448 F.Supp.2d 737 (E.D.La.,2006); *In re* Vioxx Products Liability Litigation, *448 F.Supp.2d 737*, 739 *(E.D.La. 2006)*.

199. *Philip Morris USA v. Williams*, 549 U.S. 346, 356-57 (2007) (constitutionally protected defenses include individualized inquiries such as a plaintiff's knowledge); Cf. *Dukes v. Wal-Mart, Inc.*, 474 F.3d 1214, 1242 (9th Cir. 2007) (statistical formulas are employed to fashion the appropriate remedy).

ance. These, and other questions regarding punitive damages, will be heard in future trials.[200]

C. Trace Back Liability

The consolidated LL601 litigation also includes the claim of the German rice importing company (Rickmers), which is suing for breach of contract. Rickmers, by suing the grower cooperative Riceland, hopes to recover its losses via trace back liability through the chain of commerce. Riceland, in turn, however, may find its remedies against the originating seed company (Bayer) limited due to the seed industry's adept use of liability disclaimers in adhesion contracts signed by growers. In the LL601 litigation, the rice grower cooperative Riceland conceivably could sue Bayer to recover amounts paid due to the commingling caused by Bayer. This may prove difficult, however, if the growers in the cooperative purchased seed with disclaimers of liability from Bayer (and those disclaimers or limitations of liability are enforced to deny recovery by Riceland of amounts paid to claimants such as Rickmers). Seed contracts typically have boilerplate disclaimers of liability for traces of genetic "off-types," which might include biotech crops that were never submitted for regulatory approval in the U.S., much less the overseas markets at issue in the LL601 rice case.[201]

On the other hand, it its LL601 summary judgment ruling, the court found little reason to hold the handlers such as Riceland liable for any degree of comparative fault. Bayer asserted that it could not have caused the harm in question "due to the intervening and/or superseding acts or omissions of parties or non-parties to this action for whose acts or omissions the BCS Defendants and Bayer Corporation are not liable."[202]

The court, however, held that "[a]lthough plaintiffs still have to prove proximate cause, Bayer may not argue that others may have caused the losses. . . . the negligence, if there was any, was in Bayer's handling of the GM rice that it controlled. . . . [t]he risk that the GM trait might escape and contaminate other non-GM rice or other plants is precisely the known and foreseeable risk that Bayer under-

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200. *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d at 1031.

201. *See* A. Bryan Endres, *Revising Seed Purity Law to Account for the Adventitious Presence of Genetically Modified Varieties: A First Step Toward Coexistence*, 1 J. FOOD L. & POL'Y 131,154-55 (2005) (discussing liability disclaimers in seed purchase contracts).

202. *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d at 1024.

took when it field tested the rice. Bayer's duty included the duty to assure that those it chose to field test the rice followed proper procedures."[203] Accordingly, trace back liability to the seed developer, similar to the Starlink litigation, appears to have survived the first stages of the genetically modified rice litigation.

In conclusion, although the test cases thus far have imposed significant liability on Bayer, the case may not create a broad remedy at common law merely for the loss of an export market in a commodity crop. Although that might be a logical extension of the current case, it is important to note that Bayer's unauthorized release of LL601 was unlawful when it occurred, even if the subsequent regulatory review by USDA removed any duty to conduct a recall of rice in domestic markets. In contrast, a seed company that is fully compliant with U.S. regulations, and also undertakes disclosure of the regulatory approval (or lack thereof) of the seed being sold via a disclaimer in the seed purchase contract, may have *less* evidence of negligence than Bayer (with its alleged lack of oversight of its LL601 field trials). Moreover, although in this case the court denied Bayer's LLP-based defenses, eventual APHIS finalization of a revised LLP rule that authorizes limited commingling of even regulated genetically modified plant varieties (i.e., biotech varieties not yet approved for commercial release) could preclude plaintiffs in the future from seeking compensation for lost markets via trace back liability to the seed developer. As a result, it could leave food processors or others in the food supply chain exposed to breach of contract actions (e.g., breach of contract for failure to deliver food meeting required purity standards) as they would be unable to recover their losses from the biotechnology company initially responsible for the product commingling.

V. CONCLUDING THOUGHTS

Unintended components incorporated into the food supply, whether unapproved GM or pathogens such as *V. Vulnificus* or *Salmonella* Enteritidis, present continuing challenges to a regulatory system straining to oversee global supply chains, multiple-scale farming operations and consumer demand for wholesome, unprocessed and inexpensive food. With so many facets, the Food Safety Working Group faces a difficult challenge as it attempts to realign the

203. *Id.* at 1024-25 (discussing Bayer's affirmative defense for intervening causation).

nation's food safety system within the context of multiple non-food policy initiatives such as health care, financial services reform, global climate change legislation and immigration reform. As noted in the opening paragraph, many of these relatively small initiatives discussed within this article may coalesce into a comprehensive reform of the food regulatory system from farm to fork. On the other hand, political realities may impose substantial roadblocks and divert attention to more immediate needs. Nonetheless, the second half of 2009 witnessed several potentially significant food law issues with long-term impact.

European Union Food Law Update:
A Special Look at the Treaty of Lisbon
and its Impact on European
Agricultural Policy by Emilie H. Leibovitch